UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 10-Q

(Mark One)

x QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended June 30, 2021

Or

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from to

Commission File Number: 001-34899

Pulse Biosciences, Inc.
(Exact name of registrant as specified in its charter)

Delaware **(State or other jurisdiction of incorporation or organization)**		**46-5696597** **(I.R.S. Employer Identification No.)**
3957 Point Eden Way **Hayward, CA** **(Address of principal executive offices)**		**94545** **(Zip Code)**

(510) 906-4600
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.001 per share	**PLSE**	**The Nasdaq Stock Market**

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes x No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	x	Smaller reporting company	x
		Emerging growth company	x

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. x

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No x

The number of shares outstanding of the registrant's common stock as of July 31, 2021: 29,605,930

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"Pulse Biosciences," the Pulse logos and other trademarks or service marks that we use in connection with the operation of our business appearing in this quarterly report on Form 10-Q (this "Quarterly Report"), including CellFX, CellFX CloudConnect, CellFX Marketplace, Nano-pulse Stimulation, and NPS, are the property of Pulse Biosciences, Inc. Solely for your convenience, some of our trademarks and trade names referred to in this Quarterly Report are listed without the ® and TM symbols, but we will assert, to the fullest extent under applicable law, our rights to our trademarks and trade names. Also, this Quarterly Report may contain additional trade names, trademarks or service marks of others, which are the property of their respective owners. We do not intend our use or display of any other company's trade names, trademarks or service marks to imply a relationship with, or endorsement or sponsorship of us by, any of these other companies.

Unless expressly indicated or the context requires otherwise, the terms "Pulse," "company," "we," "us," and "our," in this document refer to Pulse Biosciences, Inc., a Delaware corporation, and, where appropriate, its wholly owned subsidiaries.

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

PULSE BIOSCIENCES, INC.
Condensed Consolidated Balance Sheets
(In thousands, except per share amounts)
(Unaudited)

	June 30, 2021	December 31, 2020
ASSETS		
Current assets:		
Cash and cash equivalents	$ 47,426	$ 12,463
Investments	—	8,012
Inventory	2,691	—
Related party other receivable (Note 6)	8,371	1,223
Prepaid expenses and other current assets	3,267	641
Total current assets	61,755	22,339
Property and equipment, net	2,460	2,478
Intangible assets, net	3,549	3,882
Goodwill	2,791	2,791
Right-of-use assets	9,119	9,438
Other assets	365	365
Total assets	$ 80,039	$ 41,293
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 2,823	$ 1,717
Accrued expenses	4,572	5,326
Lease liability, current	719	542
Note payable, current	1,730	—
Total current liabilities	9,844	7,585
Lease liability, less current	10,445	10,814
Total liabilities	20,289	18,399
Commitments and contingencies (Note 8)		
Stockholders' equity:		
Preferred stock, $0.001 par value; authorized – 50,000 shares; no shares issued and outstanding	—	—
Common stock, $0.001 par value: authorized – 500,000 shares; issued and outstanding – 29,606 shares and 25,550 shares at June 30, 2021 and December 31, 2020, respectively	29	25
Additional paid-in capital	266,223	195,410
Accumulated other comprehensive income (loss)	—	(1)
Accumulated deficit	(206,502)	(172,540)
Total stockholders' equity	59,750	22,894
Total liabilities and stockholders' equity	$ 80,039	$ 41,293

See accompanying notes to the condensed consolidated financial statements.

PULSE BIOSCIENCES, INC.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(In thousands, except per share amounts)
(Unaudited)

	Three-Month Periods Ended June 30,		Six-Month Periods Ended June 30,	
	2021	2020	2021	2020
Revenue	$ —	$ —	$ —	$ —
Operating expenses:				
Research and development	7,459	5,870	16,522	12,051
Sales and marketing	3,147	1,485	7,293	3,180
General and administrative	4,200	3,999	9,516	8,073
Total operating expenses	14,806	11,354	33,331	23,304
Other income (expense):				
Interest income (expense), net	(517)	21	(631)	99
Total other income (expense)	(517)	21	(631)	99
Net loss	(15,323)	(11,333)	(33,962)	(23,205)
Other comprehensive gain (loss):				
Unrealized gain (loss) on available-for-sale securities	—	(17)	1	(4)
Comprehensive loss	$ (15,323)	$ (11,350)	$ (33,961)	$ (23,209)
Net loss per share:				
Basic and diluted net loss per share	$ (0.58)	$ (0.53)	$ (1.29)	$ (1.10)
Weighted average shares used to compute net loss per common share — basic and diluted	26,477	21,528	26,276	21,183

See accompanying notes to the condensed consolidated financial statements.

PULSE BIOSCIENCES, INC.
Condensed Consolidated Statements of Cash Flows
(In thousands)
(Unaudited)

	Six-Month Periods Ended June 30,	
	2021	2020
Cash flows from operating activities:		
Net loss	$ (33,962)	$ (23,205)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	229	213
Amortization of intangible assets	333	333
Stock-based compensation	9,413	5,038
Net premium amortization and discount on available-for-sale securities	13	(1)
Loss on disposal of fixed assets	—	119
Gain on U.S. Treasury securities	—	(8)
Changes in operating assets and liabilities:		
Inventory	(2,691)	—
Prepaid expenses and other current assets	(2,454)	522
Other receivables	23	—
Right-of-use assets	319	198
Other long-term assets	—	129
Accounts payable	1,041	(758)
Accrued expenses	(754)	393
Lease liabilities	(192)	(110)
Accrued interest on related party note	629	—
Other assets	—	(424)
Net cash used in operating activities	(28,053)	(17,561)
Cash flows from investing activities:		
Purchases of property and equipment	(146)	(100)
Purchases of investments	—	(3,006)
Maturities of investments	8,000	17,000
Sale of investments	—	4,510
Net cash provided by investing activities	7,854	18,404
Cash flows from financing activities:		
Proceeds from issuance of common stock under employee stock purchase plan	421	255
Proceeds from exercises of warrants	4,217	—
Proceeds from exercises of stock options	678	9
Proceeds from issuance of common stock	48,348	29,759
Proceeds from insurance loan agreement	1,730	—
Tax payments related to shares withheld for vested restricted stock units	(232)	—
Net cash provided by financing activities	55,162	30,023
Net increase in cash	34,963	30,866
Cash and cash equivalents at beginning of period	12,463	6,899
Cash and cash equivalents at end of period	$ 47,426	$ 37,765
Supplemental disclosure of noncash investing and financing activities:		
Equipment purchases included in accounts payable and accrued expenses	$ 65	$ 257
Change in unrealized gains on available-for-sale securities	1	(4)
Accrued interest settled via issuance of common stock from private placement equity offering from private placement equity offering	629	—
Related party other receivable from issuance of common stock from private placement equity offering	8,371	—
Other receivable from issuance of common stock from at-the-market equity offering	25	—
Issuance costs for rights offering in accounts payable	—	261

See accompanying notes to the condensed consolidated financial statements.

PULSE BIOSCIENCES, INC.
Condensed Consolidated Statements of Stockholders' Equity
(In thousands)
(Unaudited)

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance, March 31, 2021	26,401	$ 26	$ 211,550	$ —	$ (191,179)	$ 20,397
Issuance of common stock as part of debt extinguishment and private investment, net of issuance cost of $59	3,049	3	49,938	—	—	49,941
Issuance of common stock as part of ATM offering	131	—	2,469	—	—	2,469
Issuance of common stock upon exercise of stock options	5	—	59	—	—	59
Issuance of common stock upon vesting of restricted stock units, net of shares withheld for employee taxes	22	—	(232)	—	—	(232)
Adjustment to shares issued under employee stock purchase plan	(2)	—	(9)	—	—	(9)
Stock-based compensation expense	—	—	2,448	—	—	2,448
Unrealized gain on available-for-sale securities	—	—	—	—	—	—
Net loss	—	—	—	—	(15,323)	(15,323)
Balance, June 30, 2021	29,606	$ 29	$ 266,223	$ —	$ (206,502)	$ 59,750

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance, December 31, 2020	25,550	25	195,410	(1)	(172,540)	$ 22,894
Issuance of common stock as part of debt extinguishment and private investment, net of issuance cost of $59	3,049	3	49,938	—	—	49,941
Issuance of shares upon exercise of warrants	585	1	3,333	—	—	3,334
Issuance of common stock as part of ATM offering	288	—	7,432	—	—	7,432
Issuance of common stock upon exercise of stock options	45	—	508	—	—	508
Issuance of shares under employee stock purchase plan	67	—	421	—	—	421
Issuance of common stock upon vesting of restricted stock units, net of shares withheld for employee taxes	22	—	(232)	—	—	(232)
Stock-based compensation expense	—	—	9,413	—	—	9,413
Unrealized gain on available-for-sale securities	—	—	—	1	—	1
Net loss	—	—	—	—	(33,962)	(33,962)
Balance, June 30, 2021	29,606	$ 29	$ 266,223	$ —	$ (206,502)	$ 59,750

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance, March 31, 2020	20,869	$ 21	$ 156,291	$ 17	$ (134,561)	$ 21,768
Issuance of common stock and warrants in connection with rights offering, net of issuance cost of $501	4,280	4	29,494	—	—	29,498
Stock-based compensation expense	—	—	2,412	—	—	2,412
Unrealized gain on available-for-sale securities	—	—	—	(17)	—	(17)
Net loss	—	—	—	—	(11,333)	(11,333)
Balance, June 30, 2020	25,149	$ 25	$ 188,197	$ —	$ (145,894)	$ 42,328

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance, December 31, 2019	20,825	21	153,401	4	(122,689)	$ 30,737
Issuance of shares upon exercise of stock options	1	—	9	—	—	9
Issuance of shares under employee stock purchase plan	43	—	255	—	—	255
Issuance of common stock and warrants in connection with rights offering, net of issuance cost of $501	4,280	4	29,494	—	—	29,498
Stock-based compensation expense	—	—	5,038	—	—	5,038
Unrealized gain on available-for-sale securities	—	—	—	(4)	—	(4)
Net loss	—	—	—	—	(23,205)	(23,205)
Balance, June 30, 2020	25,149	$ 25	$ 188,197	$ —	$ (145,894)	$ 42,328

See accompanying notes to the condensed consolidated financial statements.

PULSE BIOSCIENCES, INC.
Notes to Condensed Consolidated Financial Statements
(Unaudited)

1. Description of the Business

Pulse Biosciences, Inc. is a novel bioelectric medicine company committed to health innovation using an entirely new and proprietary energy modality. The Company's CellFX® System is the first commercial product to harness the distinctive advantages of the Company's proprietary Nano-Pulse Stimulation™ ("NPS") technology. The CellFX System delivers nano second duration pulses of electrical energy, each less than a millionth of a second long, to non-thermally clear targeted cells while sparing adjacent non-cellular tissue, to treat a variety of medical conditions for which an optimal solution remains unfulfilled.

In February 2021, the Company received 510(k) clearance from the U.S. Food and Drug Administration (the "FDA") for the CellFX System with initial clearance for a general indication for dermatologic procedures requiring ablation and resurfacing of the skin. In January 2021, the Company received Conformité Européene (CE) marking approval for the CellFX System, which allows for marketing of the system in the European Union (EU), and in June 2021, the Company received Health Canada approval for the CellFX System, which allows for marketing of the system in Canada. The CE mark and and Health Canada approvals allow for use of the CellFX System in dermatological procedures requiring ablation and resurfacing of the skin for the reduction, removal, and/or clearance of cellular-based benign lesions, including SH, SK, and cutaneous non-genital warts. The Company has commenced a controlled launch in these three regions with key opinion leaders in dermatology (Note 9).

The Company was incorporated in Nevada on May 19, 2014. On June 18, 2018, the Company reincorporated from the State of Nevada to the State of Delaware. The Company is located in Hayward, California.

The Company's activities are subject to significant risks and uncertainties, including the need for additional capital. The Company has not yet commenced any revenue-generating operations, does not have any cash flows from operations, and will need to raise additional capital to finance its operations. However, there can be no assurances that the Company will be able to obtain additional financing on acceptable terms and in the amounts necessary to fully fund its operating requirements.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements have been prepared on a basis consistent with the Company's December 31, 2020 audited Consolidated Financial Statements and include all adjustments, consisting of only normal recurring adjustments, necessary to fairly state the information set forth herein. The condensed consolidated financial statements have been prepared in accordance with the applicable rules and regulations of the Securities and Exchange Commission (the "SEC") and, as permitted by such rules and regulations, omit certain information and footnote disclosures necessary to present the financial statements in accordance with accounting principles generally accepted in the United States ("U.S. GAAP"). The condensed consolidated balance sheet as of December 31, 2020 was derived from the audited consolidated financial statements as of that date but does not include all of the information and footnotes required by U.S. GAAP for complete financial statements. These condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto included in the Company's Annual Report on Form 10-K for the year ended December 31, 2020. The results of operations for the three-month and six-month periods ended June 30, 2021 are not necessarily indicative of the results to be expected for the entire year or any future periods.

Certain prior period balances have been reclassified to conform to the current period presentation in the consolidated financial statements and the accompanying notes. Sales and marketing expenses are reclassified out of general and administrative expenses, both of which are presented as separate line items. Amortization of intangible assets are reclassified to general and administrative expenses.

Principles of Consolidation

The accompanying condensed consolidated financial statements include the financial statements of Pulse Biosciences, Inc. and its wholly-owned subsidiaries. Intercompany balances and transactions, if any, have been eliminated in consolidation.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires the Company to make estimates and assumptions that affect the amounts reported in the Financial Statements and accompanying notes to the condensed consolidated financial statements. Estimates include, but are not limited to, the valuation of cash equivalents and investments, the valuation and recognition of share-based compensation and the useful lives assigned to long-lived assets. The Company evaluates its estimates and assumptions based on historical experience and other factors and adjusts those estimates and assumptions when facts and circumstances dictate. Actual results could differ materially from these estimates.

Significant Accounting Policies

The Company's significant accounting policies are described in the Company's Annual Report on Form 10-K for the year ended December 31, 2020. The Company continually evaluates the accounting policies and estimates used in preparing the consolidated financial statements. During the six-month period ended June 30, 2021, the Company received 510(k) clearance, CE marking approval, and Health Canada clearance for their proprietary CellFX System and began to capitalize inventory in preparation for commercialization.

Valuation of Inventory

Inventory is stated at lower of cost or net realizable value. The Company establishes the inventory basis by determining the cost based on standard costs approximating the purchase costs on a first-in, first-out basis. Net realizable value is the estimated selling price in the ordinary course of the Company's business, less reasonably predictable costs of completion, disposal, and transportation. The cost basis of the Company's inventory will be reduced for any products that are considered excessive or obsolete based upon assumptions about future demand and market conditions. At June 30, 2021, there is no reduction to the balance of inventory for excessive and obsolete inventory.

Net Loss per Share

The Company calculates basic net loss per share by dividing net loss by the weighted-average number of shares of common stock outstanding during the period. Diluted net loss per share is computed by giving effect to all potential dilutive common stock equivalents outstanding during the period. For purposes of this calculation, options to purchase common stock and common stock warrants are considered common stock equivalents. Potential common shares that have an anti-dilutive effect (*i.e.*, those that increase income per share or decrease loss per share) are excluded from the calculation of diluted net loss per share.

Basic and diluted net loss per common share is the same for all periods presented because all warrants, stock options and restricted stock units outstanding are anti-dilutive.

The following outstanding stock options, warrants and restricted stock units were excluded from the computation of diluted net loss per share for the periods presented because including them would have had an anti-dilutive effect:

	Six-Month Periods Ended June 30,	
	2021	2020
Common stock warrants	600	809,418
Common stock options	5,827,524	5,216,500
Restricted stock units	89,273	34,402
Total	5,917,397	6,060,320

Recent Accounting Pronouncement

In December 2019, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes*, which eliminates certain exceptions related to the general principles in Accounting Standards Codification (ASC) 740 and makes amendments to other areas with the intention of simplifying various aspects related to accounting for income taxes. The new standard is effective for fiscal years beginning after December 15, 2020, including interim periods therein; with early adoption permitted. The Company adopted the Topic 740 effective January 1, 2021. The adoption did not have a material impact on the Company's financial statements.

3. Fair Value of Financial Instruments

The authoritative guidance with respect to fair value established a fair value hierarchy that prioritizes the inputs to valuation techniques used to measure fair value into three levels, and requires that assets and liabilities carried at fair value be classified and disclosed in one of three categories, as presented below.

Level 1 - Observable inputs such as quoted prices in active markets for an identical asset or liability that the Company has the ability to access as of the measurement date. Financial assets and liabilities utilizing Level 1 inputs include money market funds.

Level 2 - Inputs, other than quoted prices included within Level 1, which are directly observable for the asset or liability or indirectly observable through corroboration with observable market data. Financial assets and liabilities utilizing Level 2 inputs include commercial paper, corporate bonds, U.S. Treasury Securities, and asset-backed securities.

Level 3 - Unobservable inputs for which there is little or no market data for the asset or liability which requires the reporting entity to develop its own assumptions. The Company did not classify any of its investments within Level 3 of the fair value hierarchy.

The following table sets forth the fair value of the Company's financial assets measured on a recurring basis as of June 30, 2021 and December 31, 2020, respectively (in thousands):

		June 30, 2021				December 31, 2020			
Assets	**Classification**	**Level 1**	**Level 2**	**Level 3**	**Total**	**Level 1**	**Level 2**	**Level 3**	**Total**
Money market funds	Cash and cash equivalents	$ 44,279	$ —	$ —	$ 44,279	$ 7,176	$ —	$ —	$ 7,176
U.S. Treasury Securities	Cash and cash equivalents	—	—	—	—	—	2,004	—	2,004
U.S. Treasury Securities	Investments	—	—	—	—	—	8,012	—	8,012
Total assets measured at fair value		$ 44,279	$ —	$ —	$ 44,279	$ 7,176	$ 10,016	$ —	$ 17,192

The Company did not have any financial liabilities measured on a recurring basis as of June 30, 2021 or December 31, 2020.

During the six-month period ended June 30, 2021, there were no transfers between Level 1, Level 2 or Level 3 assets or liabilities reported at fair value on a recurring basis and the valuation techniques used did not change compared to the Company's established practice.

4. Balance Sheet Components

Property and Equipment, Net

Property and equipment, net consisted of the following (in thousands):

	June 30, 2021	December 31, 2020
Leasehold improvements	$ 2,827	$ 2,805
Laboratory equipment	986	878
Furniture, fixtures, and equipment	569	517
Software	154	128
Construction in progress	69	66
	4,605	4,394
Less: Accumulated depreciation	(2,145)	(1,916)
Property and equipment, net	$ 2,460	$ 2,478

Depreciation expense was $0.1 million for each of the three-month periods ended June 30, 2021 and 2020 and was $0.2 million for each of the six-month periods ended June 30, 2021 and 2020.

Intangible Assets, Net

Intangible assets primarily consist of acquired licenses to utilize certain patents, know-how and technology relating to the Company's NPS technology for biomedical applications acquired from Old Dominion University Research Foundation (ODURF), Eastern Virginia Medical School, and the University of Southern California. In addition, the Company entered into a Sponsored Research Agreement with Old Dominion University's Frank Reidy Research Center for Bioelectrics, which includes certain intellectual property rights arising from the research. The Company is amortizing the intangible assets over an estimated useful life of 12 years.

Intangible assets, net consisted of the following (in thousands):

	June 30, 2021	December 31, 2020
Acquired patents and licenses	$ 7,985	$ 7,985
Less: Accumulated amortization	(4,436)	(4,103)
Intangible assets, net	$ 3,549	$ 3,882

A schedule of the amortization of intangible assets for the remainder of 2021 and the succeeding five fiscal years is as follows (in thousands):

Year Ending December 31:	
2021 (remaining 6 months)	$ 333
2022	665
2023	665
2024	665
2025	665
2026	556
Total	$ 3,549

Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	June 30, 2021	December 31, 2020
Compensation	$ 3,353	$ 3,324
Director and officer liability insurance (Note 10)	—	1,563
Clinical trial costs and fees	312	188
Professional fees	74	87
Controlled launch (Note 9)	563	—
Other	270	164
Total accrued expenses	$ 4,572	$ 5,326

5. Goodwill

In 2014, the Company acquired three companies, ThelioPulse, Inc., BioElectroMed Corp. and NanoBlate Corp. (the acquisitions), for aggregate consideration of $5.5 million. In accordance with ASC Topic 805, *Business Combinations*, the Company recorded goodwill of $2.8 million in connection with the acquisitions as the consideration paid exceeded the fair value of the net tangible assets and the intangible assets acquired.

The Company reviews goodwill for impairment at least annually or whenever changes in circumstances indicate that the carrying amount of goodwill may not be recoverable. Based on the Company's annual impairment test as of December 31, 2020 the Company determined that no impairment of goodwill existed and was not aware of any indicators of impairment at such date. In addition, there were no indicators of impairment at June 30, 2021.

6. Stockholders' Equity and Stock-Based Compensation

Private Placement Securities Purchase Agreement

On June 30, 2021, the Company entered into a Securities Purchase Agreement with Robert W. Duggan, the Company's largest stockholder and Board Chairman, pursuant to which the Company issued and sold to Mr. Duggan 3,048,780 shares of the Company's common stock, par value $0.001 per share, in a private placement (the "Private Placement"), at a price per share of $16.40, which was the market closing price on the date of the transaction. These shares were paid for through (i) the conversion of $41 million aggregate principal amount, together with all accrued and unpaid interest outstanding, owed to Mr. Duggan under the Loan Agreement by and between the Company and Mr. Duggan (Note 8), and (ii) cash in the amount of approximately $8.4 million. Upon the closing of this Private Placement and satisfaction of the outstanding debt, the Loan Agreement terminated, without any early termination fees or penalties being owed by the Company, and no additional amounts were owed to Mr. Duggan under the Loan Agreement. As of June 30, 2021, the Company had not yet received the approximately $8.4 million cash amount and recorded the balance as other receivable on the balance sheet. However, the cash proceeds from the sale were subsequently received by the Company in July 2021.

As of June 30, 2021, and after giving effect to this Private Placement, Mr. Duggan is the beneficial owner of approximately 51% of the Company's outstanding common stock.

At-the-Market Equity Offering

On February 4, 2021, the Company entered into a sales agreement (Sales Agreement) with Stifel, Nicolaus & Company, Inc. (Stifel) as sales agent, pursuant to which the Company may offer and sell, from time to time, through Stifel, up to $60.0 million in shares of common stock, by any method permitted by law deemed to be an "at-the-market" offering as defined in Rule 415 promulgated under the Securities Act of 1933, as amended. The Company has no obligation to make any sales of its common stock pursuant to such Sales Agreement. During the six-month period ended June 30, 2021, the Company issued and sold 288,490 shares of common stock under the Sales Agreement. The shares were sold at a weighted average price of $27.73 per share for aggregate net proceeds of approximately $7.4 million, after deducting sales commissions and offering costs payable by the Company. During the three-month period ended June 30, 2021, the Company issued and sold 130,748 shares of common stock under the Sales Agreement. The shares were sold at a weighted average price of $19.82 per share for aggregate net proceeds of approximately $2.5 million, after deducting sales commissions and offering costs payable by the Company.

Rights Offering

In June 2020, the Company completed a rights offering to purchase up to $30 million of units, each unit consisting of one share of the Company's common stock, par value $0.001 per share, and 0.15 warrants to purchase shares of common stock (the Units) at a price of $7.01 per Unit (the Rights Offering). The common stock and warrants comprising the Units separated upon the closing of the Rights Offering and were issued separately.

A total of 4,279,600 shares of common stock and 641,571 warrants (Rights Offering Warrants) were issued and sold in the Rights Offering for net proceeds of approximately $29.4 million. Each warrant was exercisable for one share of the Company's common stock at an exercise price equal to $7.01, the subscription price for the Units. The Rights Offering Warrants were exercisable immediately and expired on the fifth anniversary of the completion of the Rights Offering, or June 16, 2025, subject to certain redemption rights by the Company. The Rights Offering Warrants were subject to redemption by the Company, on or after December 16, 2020, six months after the issue date, for $0.01 per warrant, with not less than 30 days written notice, if the volume weighted average price of our common stock equaled or exceeded 200% of the exercise price for the Rights Offering Warrants for 10 consecutive trading days.

Common Stock Warrants

In connection with a private placement in November 2014 of the Company's common stock, par value $0.001 per share, the Company issued warrants as compensation to the placement agent to purchase a total of 299,625 shares of its common stock at an exercise price of $2.67 per share (Private Placement Warrants). The Private Placement Warrants are exercisable for period of seven years from issuance. In March 2021, warrants to purchase 45,638 shares of common stock were net exercised, resulting in the issuance of 40,563 shares of common stock. As of June 30, 2021, there were Private Placement Warrants to purchase up to 600 shares of common stock still outstanding.

In connection with the closing of the Company's initial public offering in May 2016, the Company issued warrants as compensation to its underwriters, to purchase a total of 574,985 shares of its common stock at an exercise price of $5.00 per share (IPO Warrants). The IPO Warrants were exercisable for a period of five years from issuance. In March 2021, warrants to purchase 85,385 shares of common stock were net exercised, resulting in the issuance of 68,958 shares of common stock. As of June 30, 2021, there were no IPO Warrants outstanding.

In connection with the Rights Offering, the Company issued warrants to purchase a total of 641,571 shares of its common stock at an exercise price of $7.01. On December 31, 2020, the Company met the requirements for redemption of these warrants and delivered a notice of redemption to redeem all of the outstanding warrants that remained unexercised at February 5, 2021, for the redemption price of $0.01 per warrant. Pursuant to the redemption, the Company redeemed 5,139 warrants. Prior to the February 5, 2021 redemption date, 636,432 warrants were exercised, generating approximately $4.5 million of total gross proceeds to the Company. As of June 30, 2021, there were no Rights Offering Warrants outstanding.

Equity Plans

2017 Equity Incentive Plan and 2017 Inducement Equity Incentive Plan

The Board of Directors of the Company (the "Board") previously adopted, and the Company's stockholders approved, the Company's 2017 Equity Incentive Plan (the "2017 Plan").

The 2017 Plan has a 10-year term, and provides for the grant of stock options, stock appreciation rights, restricted stock, restricted stock units, performance units, and performance shares to employees, directors and consultants of the Company and any parent or subsidiary of the Company, as the Compensation Committee of the Board may determine. Subject to an annual evergreen increase and adjustment in the case of certain capitalization events, the Company initially reserved 1,500,000 shares of the Company's common stock for issuance pursuant to awards under the 2017 Plan. In addition, shares remaining available under the Company's 2015 Equity Incentive Plan, as amended (the "2015 Plan"), and shares reserved but not issued pursuant to outstanding equity awards that expire or terminate without being exercised or that are forfeited or repurchased by the Company will be added to the shares of common stock available for issuance under the 2017 Plan. The 2017 Plan is administered by the Board's Compensation Committee. Effective January 1, 2021, the Company's Board authorized an increase in the number of shares of common stock available under the 2017 Plan by 1,022,002 shares pursuant to the evergreen provision of the 2017 Plan. Pursuant to the 2017 Plan, the 2021 share increase is determined based on the least of (i) 1,200,000 shares, (ii) 4% of the Company's common stock outstanding at December 31 of the immediately preceding year, or (iii) such number of shares as determined by the Board. As of June 30, 2021, 634,902 shares of common stock remained available for issuance under the 2017 Plan.

During November 2017, the Board adopted the 2017 Inducement Equity Incentive Plan (the "Inducement Plan") and reserved 1,000,000 shares of the Company's common stock for issuance pursuant to equity awards granted under the Inducement Plan. The Inducement Plan was adopted without stockholder approval. The Inducement Plan has a 10-year term, and provides for the grant of equity-based awards, including nonstatutory stock options, restricted stock units, restricted stock, stock appreciation rights, performance shares and performance units, and its terms are substantially similar to the 2017 Plan, including with respect to treatment of equity awards in the event of a "merger" or "change in control" as defined under the Inducement Plan. Options issued under the Inducement Plan may have a term up to ten years and have variable vesting provisions. New hire grants generally vest 25% per year starting upon the first anniversary of the grant. Equity-based awards issued under the Inducement Plan are only issuable to individuals not previously engaged as employees or as non-employee directors of the Company prior to the Inducement Plan's adoption date. In May 2021, the Board approved an amendment to the Inducement Plan to reserve an additional 1,000,000 shares of the Company's common stock for issuance pursuant to the Inducement Plan. As of June 30, 2021, 1,030,846 shares of common stock remained available for issuance under the Inducement Plan.

Certain stock options awarded to the Company's executives and other key employees contain performance conditions related to certain financial measures and achievements of strategic/operational milestones (performance options). As of June 30, 2021, not all of the performance conditions are probable to be achieved. Compensation expense has only been recognized for those conditions that are assumed to be probable.

During February 2021, Management and the Compensation Committee approved of a modification to certain vesting conditions of outstanding performance options. The Company had not recognized any compensation expense in relation to these performance options as the performance condition was previously deemed to be improbable. However, upon modification those specific performance conditions are now deemed probable and fully vested. As such, during the six-month period ended June 30, 2021, the full expense in relation to the amended performance conditions was recognized resulting in $4.2 million of additional stock-compensation expense.

A summary of stock option activity under the 2015 Plan, 2017 Plan and Inducement Plan for the six-months ended June 30, 2021 is presented below:

	Stock Options Outstanding	
	Number of shares	Weighted average exercise price
Balances — December 31, 2020	5,039,194	$ 14.26
Options granted	976,078	
Options exercised	(44,981)	
Options canceled	(80,029)	
Options expired	(62,738)	
Balances — June 30, 2021	5,827,524	$ 15.64
Exercisable — June 30, 2021	3,042,982	$ 16.00

2017 Employee Stock Purchase Plan

The Board previously adopted and the stockholders approved the Company's 2017 Employee Stock Purchase Plan (the "2017 ESPP").

The 2017 ESPP is a broad-based plan that provides employees of the Company and its designated affiliates with the opportunity to become stockholders through periodic payroll deductions that are applied towards the purchase of Company common shares at a discount from the then-current market price. Subject to adjustment in the case of certain capitalization events, a total of 250,000 common shares of the Company were available for purchase at adoption of the 2017 ESPP. Pursuant to the 2017 ESPP, the annual share increase pursuant to the evergreen provision is determined based on the least of (i) 450,000 shares, (ii) 1.5% of the Company's common stock outstanding at December 31 of the immediately preceding year, or (iii) such number of shares as determined by the Board. Effective January 1, 2021, pursuant to the evergreen provision of the 2017 ESPP, the number of shares of common stock available under the 2017 ESPP was increased by 383,250 shares. During the six-month period ended June 30, 2021, the Company issued 66,525 shares of common stock under the 2017 ESPP. As of June 30, 2021, 673,949 shares of common stock remained available for issuance under the 2017 ESPP.

Stock-based Compensation

Total stock-based compensation expense consisted of the following (in thousands):

	Three-Month Periods Ended June 30,		Six-Month Periods Ended June 30,	
	2021	2020	2021	2020
Research and development	$ 1,002	$ 897	$ 4,168	$ 1,774
Sales and marketing	500	280	2,261	590
General and administrative	946	1,235	2,984	2,674
Total stock-based compensation expense	$ 2,448	$ 2,412	$ 9,413	$ 5,038

The Company estimated the fair value of employee stock options on the grant date using the Black-Scholes option pricing model. The estimated fair value of employee stock options is amortized on a straight-line basis over the requisite service period of the awards. The Company reviews, and when deemed appropriate, updates the assumptions used on a periodic basis. Due to the limited trading history of the Company's common stock, the Company utilizes a portfolio of comparable companies to estimate volatility. The fair value of employee stock options was estimated using the following weighted-average assumptions:

	Three-Month Periods Ended June 30,		Six-Month Periods Ended June 30,	
	2021	2020	2021	2020
Expected term in years	5.3 - 6.1	5.3 - 6.1	5.3 - 6.1	5.3 - 6.1
Expected volatility	78%	70%	78%	70%
Risk-free interest rate	0.9 - 1.0%	0.4 - 0.5%	0.9 - 1.1%	0.4 - 0.5%
Dividend yield	—	—	—	—

The Company estimated the fair value of ESPP on the grant date using the Black-Scholes option pricing model. The estimated fair value of ESPP is amortized on a straight-line basis over the requisite service period of the awards. The Company reviews, and when deemed appropriate, updates the assumptions used on a periodic basis. The Company utilizes its estimated volatility in the Black-Scholes option pricing model to determine the fair value of ESPP. The fair value of ESPP was estimated using the following weighted-average assumptions:

	Three-Month Periods Ended June 30,		Six-Month Periods Ended June 30,	
	2021	2020	2021	2020
Expected term in years	0.5 - 1.0	0.5 - 1.0	0.5 - 1.0	0.5 - 1.0
Expected volatility	78%	70%	78%	70%
Risk-free interest rate	0.07 - 0.08%	0.9 - 1.0%	0.07 - 0.1%	0.9 - 1.0%
Dividend yield	—	—	—	—

7. Research Grants and Agreements

Sponsored Research Agreement

The Company may sponsor research activities (SRAs) performed by Old Dominion University's Frank Reidy Center (ODURF). ODURF is compensated by the Company for its conduct of each study in accordance with the budget and payment terms set forth in the applicable task order.

In March 2021, the Company agreed to sponsor a task order in the amount of $0.3 million for research performed during the subsequent 12-month period to be funded through monthly payments to ODURF. In May 2021, the Company agreed to sponsor an additional task order in the amount of $0.3 million for research performed during the subsequent 12-month period to be funded through monthly payments to ODURF. Payments will be made upon ODURF certifying, to the Company's reasonable satisfaction, that ODURF has met its obligations pursuant to the specified task order and statement of work. The principal investigator may transfer funds with the budget as needed without the Company's approval so long as the obligations of ODURF under the task order and statement of work remain unchanged and unimpaired.

During the three-month periods ended June 30, 2021 and 2020, the Company incurred costs relating to the SRAs equal to $0.1 million and $0.2 million, respectively; and during the six-month periods ended June 30, 2021 and 2020, incurred costs equal to $0.1 million and $0.4 million, respectively.

8. Commitments and Contingencies

Loan Agreement

On March 11, 2021, the Company and Robert W. Duggan, the Board Chairman, entered into a Loan Agreement in connection with Mr. Duggan lending the principal sum of $41.0 million to the Company. The Loan Agreement bore interest at a rate per annum equal to 5.0%, payable quarterly commencing on July 1, 2021. The interest rate payable under the Loan Agreement increases to 7.0% upon the occurrence of an Event of Default or a Material Adverse Effect, each as defined in the Loan Agreement. All unpaid principal amount of the Loan Agreement, together with any then unpaid and accrued interest, shall be payable at the earlier of (i) June 11, 2022 or (ii) when, upon the occurrence and during the continuance of an Event of Default, such amounts are declared due and payable by Mr. Duggan or made automatically due and payable, in each case, in accordance with the terms thereof, including any applicable cure periods as set forth in the Loan Agreement. A late payment fee equal to 2.0% will be applied to any payments received later than one (1) business day after the expiration of the applicable cure period. Upon five business days prior written notice to Mr. Duggan, the Company may prepay all or any portion of the amounts borrowed under the Loan Agreement, without premium or penalty. The Loan Agreement subjects the Company to certain affirmative and negative covenants. In addition, the Loan Agreement contains certain Events of Default. During the six-month periods ended June 30, 2021, the Company recorded $0.6 million of interest expense in relation to this Loan Agreement.

In June 2021, the Loan Agreement was terminated and $41.0 million principal, together with approximately $0.6 million of accrued and unpaid interest, was fully settled via issuance of the Company's common stock at a price per share of $16.40. Refer to Note 6 for additional details of the private placement sale.

Insurance Loan Agreement

On May 13, 2021, the Company secured its annual director and officer liability insurance policy. The total premiums for the policy are approximately $2.6 million, of which the Company made a down payment of $0.7 million and financed the balance of $1.9 million via an Insurance Loan Agreement. The Insurance Loan Agreement has an annual interest rate of 3.69% and requires monthly payments through February 2022, upon which the Insurance Loan Agreement will be paid in full. The outstanding principal portion of the Insurance Loan Agreement, together with any accrued and unpaid interest, is recorded as a note payable in the balance sheet.

Operating Leases

In January 2017, the Company entered into a five-year lease (the "Existing Lease") for approximately 15,700 square feet for its corporate headquarters located in Hayward, California. The lease commenced in July 2017.

In May 2019, the Company entered into Lease Amendment 1 (the "Lease Amendment") in relation to the Existing Lease and added the lease of new premises of approximately 13,300 square feet and 21,300 square feet, (Expansion Premises 1 and Expansion Premises 2, respectively). Additionally, the term of the Existing Lease was extended to be coterminous with Expansion Premises 1 and Expansion Premises 2, effective October 2029.

The Company evaluated the lease amendment under the provisions of ASC 842. It concluded that the Lease Amendment would be accounted for as a single contract with the Existing Lease because the additional lease payments due to the Lease Amendment was not commensurate with the right-of-use (the "ROU") asset granted to the Company. Though the Lease Amendment was accounted for as a single contract, the Existing Premises, Expansion Premises 1 (occupied in November 2019) and Expansion Premises 2 (occupied in May 2020) are accounted for as separate lease components. Accordingly, the Company measured and allocated consideration to each lease component as of the modification date.

Information related to the Company's ROU assets and related lease liabilities are as follows (in thousands, except for remaining lease term and discount rate):

Year Ending December 31:	
2021 (remaining 6 months)	$ 894
2022	1,806
2023	1,845
2024	1,910
2025	1,976
2026	2,046
Thereafter	6,191
Total lease payments	16,668
Less imputed interest	(5,504)
Total lease liabilities	$ 11,164
Other supplemental information:	
Current operating lease liabilities	$ 719
Non-current operating lease liabilities	10,445
Total lease liabilities	$ 11,164
Cash paid for operating lease liabilities	$ 749
Weighted average remaining lease term	8.34
Weighted average discount rate	10%

Rent expense, including common area maintenance charges, was $0.5 million for each of the three-month periods ended June 30, 2021 and 2020; and was approximately $1.0 million and $0.7 million during the six-month periods ended June 30, 2021 and 2020, respectively.

Legal Proceedings

The Company maintains indemnification agreements with its directors and officers that may require the Company to indemnify them against liabilities that arise by reason of their status or service as directors or officers, except as prohibited by applicable law.

From time to time, the Company may be involved in a variety of claims, lawsuits, investigations, and proceedings relating to securities laws, product liability, patent infringement, contract disputes, and other matters relating to various claims that arise in the normal course of the Company's business. The Company currently believes that these ordinary course matters are not material to the condensed consolidated financial statements of the business; however, the results of litigation and claims are inherently unpredictable.

9. Controlled Launch

In February 2021, the Company received 510(k) clearance from the U.S. FDA for its proprietary CellFX System with initial clearance for a general dermatologic indication. In January 2021, the Company received CE marking approval for the CellFX System, which allows for marketing of the system in the EU for treatment of general dermatologic conditions, including SH, SK, and cutaneous non-genital warts. Additionally, in June 2021 the Company received Health Canada approval for the CellFX System, which allows for marketing of the system in Canada for use in dermatological procedures requiring ablation and resurfacing of the skin for the reduction, removal, and/or clearance of cellular-based benign lesions. Having obtained clearance in these three regions, the Company has commenced a controlled launch of the CellFX System in the U.S., EU, and Canada via their CellFX Expectations Excelled Program (the Program).

The Company selected a total of approximately 80 key opinion leaders in dermatology across the U.S., EU and Canada to be the first physicians (consultants) to launch the CellFX System and the associated CellFX commercial procedures into their respective markets and geographies. The Company has executed consulting agreements to retain these key opinion leaders to participate in the Program. According to the Program plan, the Company provides and sets-up the CellFX System at each consultant's site and provides the consultant with the necessary related products and components, free of charge, to complete the requirements of the Program. Each CellFX System and any un-used component products remain the property of the Company throughout the Program. The consultant identifies and recruits up to 40 or 50 patients, dependent on the contract, for participation in the Program, performing the CellFX procedure on each of the appropriately selected patients. Under the program, the key opinion leader consultants and their patients complete evaluation surveys about their experiences with the CellFX System and provide other information helpful to the Company. Upon completion of the procedures and the survey feedback, the consultants earn either credits which can be used towards the future purchase of the CellFX System or, in some jurisdictions, fair payment for their time and effort completing the paperwork required under the Program. Credits earned and, if applicable, any other payments earned are limited to a maximum amount dependent on number of patient procedures performed. Upon completion of the maximum number of patient procedures, the consultant may choose to either enter into a purchase agreement with the Company, where they may use the credits earned (or other payments earned, as applicable) towards purchase of the CellFX System, or they shall return the CellFX System to the Company.

As patient procedures and surveys have been completed under the Program, the Company has been accruing for the value of the credits earned, which have been recorded in accrued expenses, with a corresponding charge to marketing expense. During the three-month and six-month periods ended June 30, 2021, the Company recorded $0.4 million and $0.6 million, respectively, of sales and marketing expense in relation to the Program.

10. Related Party Transactions

Kenneth A. Clark, a director of the Company since November 2017, is a member of the law firm of Wilson Sonsini Goodrich and Rosati (WSGR), which also serves as the outside corporate counsel to the Company. During the three and six-month periods ended June 30, 2021, the Company incurred expenses reported in general and administrative in the consolidated statement of operations for legal services rendered by WSGR totaling approximately $0.2 million and $0.4 million, respectively. In June 2020, the Company incurred approximately $0.4 million of legal expenses in connection with the rights offering which was offset against the gross proceeds. During the three and six-month periods ended June 30, 2021, the Company incurred an additional $0.1 million and $0.2 million, respectively, of legal expenses in connection with the at-the-market equity offering which was offset against the gross proceeds (Note 6).

In May 2020 the Company determined not to renew its director and officer liability insurance policies due to disproportionately high premiums quoted by insurance companies. Instead, Robert W. Duggan, majority stockholder and Board Chairman, and the Company entered into a letter agreement, dated May 12, 2020 (the "Letter Agreement"), pursuant to which Mr. Duggan agreed with the Company to personally provide indemnity coverage on substantially the same terms as the Company's prior coverage program for a one-year period, and deposited security for such obligations. On May 13, 2021, in accordance with terms of the Letter Agreement, the Company paid Mr. Duggan the amount of $2.5 million. The Company did not enter into a new Letter Agreement with Mr. Duggan for the subsequent policy period, and in May 2021 secured its director and officer liability insurance through third-party insurance carriers.

In June 2020, the Company completed the Rights Offering (Note 6). Mr. Duggan participated in the Rights Offering and purchased an aggregate of 2,561,873 Units.

On March 11, 2021, the Company and Mr. Duggan entered into a Loan Agreement in connection with Mr. Duggan lending the principal sum of $41.0 million to the Company (Note 8).

On June 30, 2021, the Company and Mr. Duggan entered into a Securities Purchase Agreement (Note 6), pursuant to which the Company issued and sold to Mr. Duggan 3,048,780 shares of the Company's common stock, par value $0.001 per share, in a Private Placement, at a price per share of $16.40, for an aggregate investment in the amount of $50.0 million. The shares were paid for through (i) the conversion of $41 million aggregate principal amount, together with all accrued and unpaid interest outstanding, owed to Mr. Duggan under the Loan Agreement by and between the Company and Mr. Duggan (Note 8), and (ii) cash in the amount of approximately $8.4 million. Upon the closing of this Private Placement and satisfaction of the outstanding debt, the Loan Agreement terminated, without any early termination fees or penalties being owed by the Company, and no additional amounts were owed to Mr. Duggan under the Loan Agreement.

As of June 30, 2021, and after giving effect to this Private Placement, Mr. Duggan was the beneficial owner of approximately 51% of the Company's outstanding stock.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.
You should read the following discussion and analysis of our financial condition and results of operations together with our condensed consolidated financial statements and the related notes included in this Quarterly Report on Form 10-Q and those in our Annual Report on Form 10-K.

This report contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended (the Exchange Act). Forward-looking statements relate to expectations concerning matters that are not historical facts. Words such as "anticipates," "believes," "could," "estimates," "expects," "intends," "may," "might," "plans," "projects," "will," "would," and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. These forward-looking statements include, but are not limited to, statements related to our expected business, new product introductions, results of clinical studies, expectations regarding regulatory clearance and the timing of FDA or non-US filings or approvals including meetings with FDA or non-US regulatory bodies, procedures and procedure adoption, future results of operations, future financial position, our ability to generate revenues, the anticipated mix of our revenues between procedure and system revenues, our financing plans and future capital requirements, anticipated costs of revenue, anticipated expenses, the effect of recent accounting pronouncements, our investments, anticipated cash flows, our ability to finance operations from cash flows and similar matters, the impact of the recent COVID-19 coronavirus pandemic and related public health measures on our business, and statements based on current expectations, estimates, forecasts and projections about the economies and markets in which we intend to operate and our beliefs and assumptions regarding these economies and markets. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements that we make. You should read the "Risk Factors" section of this Quarterly Report for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis. We do not assume any obligation to update any forward-looking statements.

Overview

We are a novel bioelectric medicine company committed to health innovation using an entirely new and proprietary energy modality. Our CellFX® System is the first commercial product to harness the distinctive advantages of our proprietary Nano-Pulse Stimulation technology. The CellFX System delivers nano second duration pulses of electrical energy, each less than a millionth of a second long, to non-thermally clear targeted cells while sparing adjacent non-cellular tissue, to treat a variety of medical conditions for which an optimal solution remains unfulfilled.

In February 2021, we received 510(k) clearance from the FDA for our proprietary CellFX System with initial clearance for a general indication for dermatologic procedures requiring ablation and resurfacing of the skin. With FDA clearance, in February 2021 we commenced a controlled launch in the United States with key opinion leaders in dermatology. Following this general dermatologic indication, we plan to pursue specific indications for the CellFX System, starting with an indication for the treatment of SH lesions. This will require an additional 510(k) submission, as will each subsequent indication, and will likely be based on comparative clinical data.

In January 2021, we received CE marking approval for the CellFX System, which allows us to market the system in the European Union, and in June 2021, we received Health Canada approval for the CellFX System, which allows for marketing of the system in Canada. We have initiated a controlled launch to medical practices within these two regions for use in dermatological procedures requiring ablation and resurfacing of the skin for the reduction, removal, and/or clearance of cellular-based benign lesions, including SH, SK, and cutaneous non-genital warts.

Plan of Operation

We plan to establish ourselves as a medical therapy company with a local, non-thermal, and drug-free treatment platform that initiates cell death in targeted tissue by a process of cell signaling and also induces an adaptive immune response to the targeted tissue. In order to accomplish this, we plan to:

- Improve our technology by continuing our research and product development efforts. We expect to develop interchangeable tissue applicators to target different tissue types that will leverage the novel characteristics of our technology platform.

- Further explore and understand the benefits of our NPS technology platform with the objectives of broadening the currently planned cosmetic and therapeutic applications and identifying new applications. We anticipate that results of our clinical studies will enable us to recognize certain unmet medical needs that may be addressed by our technology.

- Continue to protect and expand our intellectual property portfolio with respect to NPS technology, which we expect will increase our ability to deter competitors and position our company for favorable licensing and partnering opportunities.

- Partner with medical or biomedical device companies for certain applications which we anticipate may accelerate product development and acceptance into target market areas and allow us to gain the sales and marketing advantages of one or more established distribution infrastructures.

COVID-19 Pandemic

Our clinical trials may be affected by the COVID-19 pandemic. Site initiation and patient enrollment may be delayed, for example, due to prioritization of hospital resources toward the COVID-19 pandemic, travel restrictions imposed by governments, and the inability to access sites for initiation and monitoring. Also, it is possible that delivery from some of our suppliers of certain materials used in the production of our product candidates could be delayed due to COVID-19 which could affect our ability to obtain sufficient materials for our product candidates. COVID-19 has and will continue to adversely affect global economies and financial markets, resulting in an economic downturn that could affect demand for our product candidates and impact our operating results. Even after the COVID-19 pandemic has subsided, we may continue to experience an adverse impact to our business as a result of the continued global economic impact of the pandemic. We cannot anticipate all of the ways in which health epidemics such as COVID-19 could adversely impact our business. Although we are continuing to monitor and assess the effects of the COVID-19 pandemic on our business, the ultimate impact of the COVID-19 pandemic or a similar health epidemic is highly uncertain and subject to change. See the Risk Factors section for further discussion of the possible impact of the COVID-19 pandemic on our business.

Critical Accounting Policies and Estimates

The discussion and analysis of our financial condition and results of operations are based upon our unaudited condensed consolidated financial statements, which have been prepared in accordance with the rules and regulations of the SEC. The preparation of these condensed consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues, and expenses. On an ongoing basis, we evaluate our critical accounting policies and estimates. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

Our significant accounting policies and estimates are described in our Annual Report on Form 10-K for the year ended December 31, 2020. We continually evaluate the accounting policies and estimates used in preparing the consolidated financial statements. During the six-month period ended June 30, 2021, the Company received 510(k) clearance, CE marking approval, and Health Canada clearance for the CellFX System and began to capitalize inventory in preparation of commercialization.

Valuation of Inventory

Inventory is stated at lower of cost or net realizable value. We established the inventory basis by determining the cost based on standard costs approximating the purchase costs on a first-in, first-out basis. Net realizable value is the estimated selling price in the ordinary course of our business, less reasonably predictable costs of completion, disposal, and transportation. The cost basis of our inventory will be reduced for any products that are considered excessive or obsolete based upon assumptions about future demand and market conditions. At June 30, 2021, there is no reduction to the balance of inventory for excessive and obsolete inventory.

Recent Accounting Pronouncements

Refer to “Recent Accounting Pronouncements” in Note 2 of Notes to Condensed Consolidated Financial Statements of this Quarterly Report.

Segment and Geographical Information

We operate and manage our business as one reportable and operating segment. Our Chief Executive Officer, who is the chief operating decision maker, reviews financial information on an aggregate basis for purposes of allocating resources and evaluating financial performance. All of our long-lived assets are based in the United States.

Results of Operations

Comparison of the three-month periods ended June 30, 2021 and 2020

Our condensed consolidated statements of operations as discussed herein are presented below:

	Three-Month Periods Ended June 30,		
(in thousands)	**2021**	**2020***	**$ Change**
Revenue	$ —	$ —	$ —
Operating expenses:			
Research and development	7,459	5,870	1,589
Sales and marketing	3,147	1,485	1,662
General and administrative	4,200	3,999	201
Total operating expenses	14,806	11,354	3,452
Other income (expense):			
Interest income (expense), net	(517)	21	(538)
Total other income (expense)	(517)	21	(538)
Net loss	$ (15,323)	$ (11,333)	$ (3,990)

* Certain 2020 amounts have been reclassified to conform to the current period presentation. Sales and marketing expenses have been reclassified out of general and administrative and presented as a separate line item. Amortization of intangible assets have been reclassified to general and administrative expenses.

Research and Development

Research and development expenses consist of compensation and other related employee expenses for research and development personnel, clinical trials and consulting costs related to the design, development and enhancement of our potential future products, prototype material and devices. Research and development expenses increased by $1.6 million to $7.5 million for the three-month period ended June 30, 2021, from $5.9 million during the same period in 2020 primarily due to $0.9 million of increased compensation and other employee related expenses, $0.5 million of increased clinical trial and other outside research costs, and $0.2 million in prototype material and devices. Compensation costs increased primarily due to headcount growth, while consulting and outside services increased primarily due to new application development, medical research and studies. Additionally, research and development expenses were partially offset by manufacturing absorption related to inventory production.

Sales and Marketing

Sales and marketing expenses consist of compensation and other related employee expenses for sales and marketing personnel, expenses associated with advertising and training, and marketing studies including our controlled launch program. Sales and marketing expenses increased by $1.7 million to $3.1 million for the three-month period ended June 30, 2021, from $1.5 million during the same period in 2020 primarily due to $0.8 million of increased compensation and other employee related expenses related to increased headcount, $0.4 million of controlled launch expenses, $0.2 million of increased paid services primarily related to market research studies and commercial preparations, and $0.2 million of increased stock-based compensation. The increases in sales and marketing activities are attributable to our FDA clearance, CE marking approval, and Health Canada clearance as we commercialize our CellFX System.

General and Administrative

General and administrative expenses consist of compensation and other related employee expenses for executives, finance, legal, human resources, information technology, and administrative personnel, professional fees, patent fees and costs, insurance costs and other general corporate expenses. General and administrative expenses increased by $0.2 million to $4.2 million for the three-month period ended June 30, 2021, from $4.0 million during the same period in 2020 primarily due to $0.5 million of increased compensation and other employee related expenses driven largely by headcount growth and $0.1 million of increased paid services. These increases were offset by $0.3 million of reduced stock-based compensation.

Other Income (Expense)

Interest expense increased by $0.5 million to $0.5 million for the three-month period ended June 30, 2021, from zero during the same period in 2020 due to the Loan Agreement entered into in March 2021 and Insurance Loan Agreement entered into in May 2021. Interest income decreased by $0.02 million primarily due to decreased investment activity.

Comparison of the six-month periods ended June 30, 2021 and 2020

Our condensed consolidated statements of operations as discussed herein are presented below:

	Six-Month Periods Ended June 30,		
(in thousands)	2021	2020	$ Change
Revenue	$ —	$ —	$ —
Operating expenses:			
Research and development	16,522	12,051	4,471
Sales and marketing	7,293	3,180	4,113
General and administrative	9,516	8,073	1,443
Total operating expenses	33,331	23,304	10,027
Other income (expense):			
Interest income (expense), net	(631)	99	(730)
Total other income (expense)	(631)	99	(730)
Net loss	$ (33,962)	$ (23,205)	$ 10,757

* Certain 2020 amounts have been reclassified to conform to the current period presentation. Sales and marketing expenses have been reclassified out of general and administrative and presented as a separate line item. Amortization of intangible assets have been reclassified to general and administrative expenses.

Research and Development

Research and development expenses consist of compensation and other related employee expenses for research and development personnel, clinical trials and consulting costs related to the design, development and enhancement of our potential future products, prototype material and devices. Research and development expenses increased by $4.5 million to $16.5 million for the six-month period ended June 30, 2021, from $12.1 million during the same period in 2020 primarily due to $2.4 million of increased stock-based compensation, $1.5 million of increased compensation and other employee related expenses, and $0.8 million of increased clinical trial and other outside research costs. These increases were partially offset by a decrease of $0.2 million in prototype material and devices. Compensation costs increased primarily due to headcount growth, while consulting and outside services increased primarily due to new application development, medical research and studies. Additionally, research and development expenses were partially offset by manufacturing absorption related to inventory production.

Sales and Marketing

Sales and marketing expenses consist of compensation and other related employee expenses for sales and marketing personnel, expenses associated with advertising and training, and marketing studies including our controlled launch program. Sales and marketing expenses increased by $4.1 million to $7.3 million for the six-month period ended June 30, 2021, from $3.2 million during the same period in 2020 primarily due to $1.7 million increased stock-based compensation, $1.3 million of increased compensation and other employee related expenses related to increased headcount, $0.6 million of controlled launch expenses, and $0.5 million of increased paid services primarily related to market research studies and commercial preparations. The increases in sales and marketing activity are attributable to our FDA clearance, CE marking approval, and Health Canada clearance as we commercialize our CellFX System.

General and Administrative

General and administrative expenses consist of compensation and other related employee expenses for executives, finance, legal, human resources, information technology and administrative personnel, professional fees, patent fees and costs, insurance costs and other general corporate expenses. General and administrative expenses increased by $1.4 million to $9.5 million for the six-month period ended June 30, 2021, from $8.1 million during the same period in 2020 primarily due to $1.0 million of increased compensation and other employee related expenses driven largely by headcount growth, $0.3 million increased stock-based compensation, and $0.2 million of increased paid services.

Other Income (Expense)

Interest expense increased by $0.6 million to $0.6 million for the six-month period ended June 30, 2021, from zero during the same period in 2020 due to the Loan Agreement entered into in March 2021 and Insurance Loan Agreement entered into in May 2021. Interest income decreased by $0.1 million primarily due to decreased investment activity.

Liquidity and Capital Resources

To date, we have not generated any revenues from product sales. Since inception, we have funded our business primarily through the issuance of equity securities and debt. Over the next few years, we intend to invest in research and development to develop new applications for existing products and additional commercially viable products and to assess the feasibility of potential future products. Additionally, we expect that our general and administrative expenses will increase as we continue to incur substantial incremental costs associated with being a public company and our sales and marketing expenses will increase as we commercialize our CellFX System.

In June 2020, we completed a rights offering pursuant to which we sold an aggregate of 4,279,600 shares of our common stock, par value $0.001 per share, and 641,571 warrants, for net proceeds of $29.4 million. On December 31, 2020, the Company met the requirements for redemption of these warrants. Pursuant to the redemption, the Company redeemed 5,139 warrants at a redemption price of $0.01 per warrant. 636,432 warrants were exercised, generating approximately $4.5 million of additional net proceeds to the Company.

On February 4, 2021, we entered into a Sales Agreement with Stifel as sales agent, pursuant to which we may offer and sell, from time to time, through Stifel, up to $60.0 million in shares of our common stock, by any method permitted by law deemed to be an “at-the-market” offering as defined in Rule 415 promulgated under the Securities Act of 1933, as amended. We have no obligation to make any sales of our common stock pursuant to such Sales Agreement. During the six-month period ended June 30, 2021, the Company issued and sold 288,490 shares of common stock under the Sales Agreement. The shares were sold at a weighted average price of $27.73 per share for aggregate net proceeds of approximately $7.4 million, after deducting sales commissions and offering costs payable by us.

In March 2021 we entered into a Loan Agreement with Robert W. Duggan, our Board Chairman, in connection with Mr. Duggan lending the principal sum of $41.0 million to the Company. The Loan Agreement had a maturity date of June 11, 2022. Under the Loan Agreement, Mr. Duggan provided us, subject to certain conditions, an unsecured term loan facility in an original aggregate principal amount of $41.0 million. The Loan Agreement bore interest at a rate per annum equal to 5.0%, payable quarterly commencing on July 1, 2021. The Loan Agreement contained certain covenants and Events of Default.

On June 30, 2021, we entered into a Securities Purchase Agreement with Mr. Duggan, pursuant to which the Company issued and sold to Mr. Duggan 3,048,780 shares of the Company’s common stock, par value $0.001 per share, in a private placement, at a price per share of $16.40. The shares were paid for through (i) the conversion of $41 million aggregate principal amount, together with all accrued and unpaid interest outstanding, pursuant to the Loan Agreement by and between the Company and Mr. Duggan (Note 8), and (ii) cash in the amount of approximately $8.4 million. Upon closing of this Private Placement and satisfaction of the outstanding debt, the Loan Agreement was terminated, without early termination fees or penalties being owed by the Company, and no additional amounts were owed to Mr. Duggan under the Loan Agreement. As of June 30, 2021, the Company had not yet received the approximately $8.4 million cash amount and recorded the balance as other receivable on the balance sheet. However, the cash proceeds from the sale were subsequently received by the Company in July 2021.

Our condensed consolidated statements of cash flows as discussed herein are presented below:

(in thousands)	Six-Month Periods Ended June 30, 2021	2020
Net cash used in operating activities	$ (28,053)	$ (17,561)
Net cash provided by investing activities	7,854	18,404
Net cash provided by financing activities	55,162	30,023
Net increase in cash	$ 34,963	$ 30,866

At June 30, 2021, we had cash and cash equivalents of $47.4 million. We believe that our existing cash and cash equivalents will be sufficient to fund our projected operating requirements for at least the next twelve months from the filing date of this Quarterly Report on Form 10-Q. However, we plan to raise additional capital in the future. There is no assurance that the at-the-market equity offering will be successful. There is no assurance that additional financing will be available when needed or that management will be able to obtain financing on terms acceptable to us.

These expectations are based on our current operating and financing plans which are subject to change. Until we are able to generate sustainable product revenues at profitable levels, we expect to finance our future cash needs through public or private equity offerings, debt financings, our at-the-market equity offering program, licensing fees for our technology, joint ventures with capital partners and project type financing. Such additional funds may not be available on terms acceptable to us or at all. If we raise funds by issuing equity or equity-linked securities, the ownership of some or all of our stockholders will be diluted and the holders of new equity securities may have priority rights over our existing stockholders. If adequate funds are not available, we may be required to curtail operations significantly or obtain funds by entering into agreements on unattractive terms. Our inability to raise capital could have a material adverse effect on our business, financial condition and results of operations.

Operating Activities

Our primary uses of cash in operating activities are for ongoing product development.

During the six-month period ended June 30, 2021, we used cash in the amount of $28.1 million in operating activities. The difference between cash used in operating activities and net loss consisted primarily of stock-based compensation, depreciation and amortization, as well as increases in inventory and prepaid and other current assets.

During the six-month period ended June 30, 2020, we used cash in the amount of $17.6 million in operating activities. The difference between cash used in operating activities and net loss consisted primarily of stock-based compensation, depreciation and amortization, and decreases in prepaid expenses and other current assets.

Investing Activities

Our investing activities consist primarily of investment purchases, sales and maturities and capital expenditures.

During the six-month period ended June 30, 2021, $7.9 million of cash provided by investing activities was primarily from $8.0 million of cash proceeds from the maturities of investments, partially offset by the purchase of property and equipment.

During the six-month period ended June 30, 2020, $18.4 million of cash provided by investing activities was primarily a result of $17.0 million of cash proceeds from the maturities of investments and $4.5 million of cash proceeds from the sale of investments, partially offset by the purchase of available-for-sale securities of $3.0 million.

Financing Activities

During the six-month period ended June 30, 2021, cash provided from financing activities was $55.2 million, primarily due to $41.0 million net cash received from our Loan Agreement, $7.4 million net cash received from our at-the-market equity offering, $4.9 million received from stock option and warrant exercises, and $0.4 million received from the sale of stock under our employee stock purchase plan.

During the six-month period ended June 30, 2020, cash provided from financing activities was $30.0 million, primarily due to cash received from our rights offering, stock option exercises and the sale of stock under our employee stock purchase plan.

Contractual Obligations

There have been no material changes outside the ordinary course of our business to the contractual obligations disclosed in our Annual Report on Form 10-K for the year ended December 31, 2020.

Off-Balance Sheet Arrangements

At June 30, 2021, we did not have any transactions, obligations or relationships that constitute off-balance sheet arrangements.

In the ordinary course of business, we enter into standard indemnification arrangements. Pursuant to these arrangements, we indemnify, hold harmless, and agree to reimburse the indemnified parties for losses suffered or incurred by the indemnified party in connection with any trade secret, copyright, patent or other intellectual property infringement claim by any third party with respect to its technology, or from claims relating to our performance or non-performance under a contract. The maximum potential amount of future payments we could be required to make under these agreements is not determinable because it involves claims that may be made against us in future periods, but have not yet been made. To date, we have not incurred costs to defend lawsuits or settle claims related to these indemnification agreements.

We also enter and have entered into indemnification agreements with our directors and officers that may require us to indemnify them against liabilities that arise by reason of their status or service as directors or officers, except as prohibited by applicable law. In addition, we may have obligations to hold harmless and indemnify third parties involved with our fundraising efforts and their respective affiliates, directors, officers, employees, agents or other representatives against any and all losses, claims, damages and liabilities related to claims arising against such parties pursuant to the terms of agreements entered into between us and such third parties in connection with such fundraising efforts. No liability associated with such indemnification agreements has been recorded as of June 30, 2021.

JOBS Act Accounting Election

Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

Trends, Events and Uncertainties

Research and development of new technologies are, by their nature, unpredictable. Although we undertake development efforts with commercially reasonable diligence, there can be no assurance that the net proceeds from our financings will be sufficient to enable us to develop our technology to the extent needed to generate future sales to sustain our operations. If we do not continue to have enough funds to sustain our operations, we will consider other options to continue the commercialization of our CellFX System, including, but not limited to, additional financing through follow-on stock offerings, debt financings, or co-development agreements and /or other alternatives.

We cannot assure investors that our technology will be adopted or that we will ever achieve sustainable revenues sufficient to support our operations. Even if we are able to generate revenues, there can be no assurances that we will be able to achieve profitability or positive operating cash flows. There can be no assurances that we will be able to secure additional financing in the future on acceptable terms or at all. If cash resources are insufficient to satisfy our ongoing cash needs, we would be required to scale back or discontinue our technology and product development programs, or obtain funds, if available, although there can be no assurances, through the sale, licensing or strategic alliances that could require us to relinquish rights to our technology and intellectual property, or to curtail, suspend or discontinue our operations entirely.

See the section entitled “COVID-19 Pandemic” above and elsewhere in this Management’s Discussion and Analysis of Financial Condition and Results of Operations for a discussion of the current and potential future impact of COVID-19 on our business, financial condition and results of operation.

Other than as discussed above and elsewhere in this Quarterly Report, we are not currently aware of any trends, events or uncertainties that are likely to have a material effect on our financial condition in the near term, although it is possible that new trends or events may develop in the future that could have a material effect on our financial condition.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Except for the broad effects of COVID-19 as a result of its negative impact on the global economy and financial markets, there have been no material changes in market risk from the information provided in our Annual Report on Form 10-K for the year ended December 31, 2020. We are exposed to market risk in the ordinary course of our business. Market risk represents the risk of loss that may impact our financial position due to adverse changes in financial market prices and rates. Our market risk exposure is primarily a result of fluctuations in interest rates. We do not hold financial instruments for trading purposes.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our management, under the supervision and with the participation of our Chief Executive Officer and our Chief Financial Officer, our principal executive and principal financial officers, respectively, conducted an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act of 1934, as amended, as of the end of the period covered by this Quarterly Report. Based on this evaluation, our Chief Executive Officer and our Chief Financial Officer have concluded that, as of June 30, 2021, our disclosure controls and procedures were effective (a) to ensure that information that we are required to disclose in reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in SEC rules and forms and (b) to include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in reports filed or submitted under the Exchange Act is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

Changes in Internal Control Over Financial Reporting

There have been no changes in our internal control over financial reporting identified in connection with the evaluation required by Rule 13a-15(d) and 15d-15(d) of the Exchange Act, as amended, that occurred during the quarter ended June 30, 2021 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting. Internal control over financial reporting means a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with U.S. GAAP.

Inherent Limitations on Effectiveness of Controls

Our management does not expect that our disclosure controls and procedures or our internal control over financial reporting will prevent all errors and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of a simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by management override of the controls. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, controls may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and may not be detected.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

From time to time, we may be involved in a variety of legal proceedings and claims relating to securities laws, product liability, patent infringement, contract disputes, employment matters, and other matters relating to the normal course of our business in addition to governmental and other regulatory investigations and proceedings. In addition, third parties may, from time to time, assert claims against us.

The results of legal proceedings and claims are inherently unpredictable. We do not believe any currently pending matters will have a material adverse effect on our business based on our current understanding of such matters. However, regardless of the outcome, any litigation could have an adverse impact on us because of defense and settlement costs, diversion of our resources and other factors.

Item 1A. Risk Factors

Investing in our common stock involves a high degree of risk. You should consider carefully the risks and uncertainties described below, together with all of the other information in this Quarterly Report, including our financial statements and related notes, which could have a material adverse effect on our business, financial condition, results of operations, and prospects. The risks described below are not the only risks facing us. Risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially affect our business, financial condition, results of operations, and prospects. In addition, the impact of COVID-19 and any worsening of the economic environment may exacerbate the risks described below, any of which could have a material impact on us.

Summary

Our business is subject to numerous risks and uncertainties that you should consider before investing in our common stock. These risks are described more fully below and include, but are not limited to, risks relating to the following:

- Our limited operating history and our lack of revenue producing operations;
- Our inability to operate without additional fundraising;
- Competition within our industry;
- Health epidemics, including the coronavirus pandemic;
- Our reliance on certain third parties such as key suppliers;
- Potential loss of key management personnel;
- Potential security breaches, loss of data, and other disruptions to us or to our third-party service providers that could compromise sensitive information;
- Potential product liability lawsuits and other litigation;
- The timing, unpredictability, and expense of our clinical and product development activities;
- The possibility of adverse trial results and unfavorable long-term trial data;
- Potential failure to obtain and maintain necessary regulatory clearances or approvals;
- Uncertainties concerning the long-term safety and effectiveness of our CellFX System and product candidates, and the potential for adverse side effects;
- The commercial uncertainties concerning whether there will be broad adoption of our CellFX System and NPS technology;

- Possible challenges enrolling patients in our clinical trials;
- Uncertainties concerning our ability to obtain an adequate level of reimbursement by Medicare and other third-party payers;
- Protection of intellectual property, potential litigation related to intellectual property, and obligations under intellectual property agreements;
- Stringent domestic and foreign regulation in respect of any potential devices and products, including healthcare laws and regulations;
- Healthcare policy changes;
- Volatility of the price of our common stock;
- Concentration of ownership by our principal stockholder and Board Chairman, Robert W. Duggan;
- Unfavorable global economic or political conditions; and
- Potential material weaknesses and uncertainties concerning our ability to maintain an effective system of internal control over financial reporting.

Risks Relating to Our Business, Industry and Financial Condition

Because we have a limited operating history and have not yet commenced any revenue producing operations, it is difficult to evaluate the future of our business.

We are a bioelectric medicine technology company and have not yet commenced revenue-producing operations. To date, our operations on a consolidated basis have consisted of the continued development and clinical studies of our technologies and implementation of the early parts of our business plan. We have incurred significant operating losses in each year since our inception and we may continue to incur additional losses for the next several years. In addition, a high percentage of our expenses will continue to be fixed; accordingly, our losses may be greater than expected and our operating results may suffer. We have limited historical financial data upon which we may base our projected revenue and base our planned operating expenses. Our limited operating history makes it difficult to evaluate our technology, operations and business prospects.

We currently have no product revenue and we may never become profitable.

To date, we have not generated revenue and we have historically relied on financing from the sale of equity securities to fund our operations. We expect that our future financial results will depend primarily on our success in launching, selling, and supporting our therapies and treatments using our CellFX System or other products based on our NPS technology. We expect to expend significant resources on hiring of personnel, continued scientific and product research and development, potential product testing and pre-clinical and clinical investigation, intellectual property development and prosecution, marketing and promotion, capital expenditures, working capital, general and administrative expenses, and fees and expenses associated with our capital raising efforts. We expect to incur costs and expenses related to consulting costs, laboratory development costs, hiring of scientists, engineers, sales representatives, and other operational personnel, and the continued development of relationships with potential partners. We are incurring significant operating losses, we expect to continue to incur additional losses for at least the next several years, and we cannot assure you that we will generate substantial revenue or be profitable in the future. There are no assurances that our future products will be cleared or approved or become commercially viable or accepted for use. Even with commercially viable applications of our technology, which may include licensing, we may never recover our research and development expenses.

Investment in medical technology is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential product will fail to demonstrate adequate efficacy or clinical utility. Investors should evaluate an investment in us in light of the uncertainties typically encountered by developing medical technology companies in a competitive environment. There can be no assurance that our efforts will be successful or that we will ultimately be able to achieve profitability. Even if we achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable could adversely affect the market price of our common stock and could significantly impair our ability to raise capital, expand our business, or continue to implement our business plan.

If we are unable to obtain sufficient funding, we may be unable to execute our business plan and fund operations. We may not be able to obtain additional financing on commercially reasonable terms, or at all.

We have experienced operating losses and we may continue to incur operating losses for the next several years as we implement our business plan. Currently, we have no revenue and, although we have implemented an at-the-market equity offering program, we do not have arrangements in place for all the anticipated financing that would be required to fully implement our business plan. Our prior losses, combined with expected future losses, have had, and will continue to have, for the foreseeable future, an adverse effect on our stockholders' equity and working capital.

We will need to raise additional capital in order to continue to execute our business plan. If we are unable to raise sufficient additional funds, we will have to scale back our operations. Also, the ongoing COVID-19 pandemic and resulting negative impact on the global macroeconomic environment and capital markets may make it more difficult for us to raise additional funds. We have incurred and may further incur additional debt.

We cannot give any assurance that we will be able to obtain all the necessary funding that we may need. In addition, we believe that we will require additional capital in the future to fully develop and bring to market our technologies and planned products. We have pursued and may pursue additional funding through various financing sources, including the private sale of our equity securities, debt financings, our an at-the-market equity offering program, licensing fees for our technology, joint ventures with capital partners, and project type financing. If we raise funds by issuing equity or equity-linked securities, dilution to some or all our stockholders would result. Any equity securities issued may also provide for rights, preferences or privileges senior to those of holders of our common stock. The terms of debt securities issued or borrowings could impose significant restrictions on our operations. We also may seek government-based financing, such as development and research grants. There can be no assurance that funds will be available on commercially reasonable terms, if at all.

Any future indebtedness could impose on us restrictive covenants, including, further limitations on our ability to incur additional debt, limitations on our ability to issue additional equity, limitations on our ability to acquire or license intellectual property rights, and other operating restrictions that could adversely affect our ability to conduct our business. In addition, the issuance of additional equity securities by us, or the possibility of such issuance, may cause the market price of our common stock to decline. Also, in the event that we enter into collaborations or licensing arrangements to raise capital, we may be required to accept unfavorable terms. These agreements may require that we relinquish, or license to a third party on unfavorable terms, our rights to technologies or product candidates that we otherwise would seek to develop or commercialize ourselves or reserve certain opportunities for future potential arrangements when we might otherwise be able to achieve more favorable terms. In addition, we may be forced to work with a partner on one or more of our products or market development programs, which could lower the economic value of those programs to us.

If we are unable to obtain adequate financing or financing on terms satisfactory to us when we require it, we may terminate or delay the development of one or more of our products, delay clinical trials necessary to market our products, or delay establishment of sales and marketing capabilities or other activities necessary to commercialize our products. If this were to occur, our ability to grow and support our business and to respond to market challenges could be significantly limited or we may be unable to continue operations, in which case you could lose your entire investment.

Our operating results may fluctuate significantly, which makes our future operating results difficult to predict and could cause our operating results to fall below expectations.

Our quarterly and annual operating results may fluctuate significantly, which makes it difficult for us to predict our future operating results. These fluctuations may occur due to a variety of factors, many of which are outside of our control and may be difficult to predict, including:

- the timing and cost of, and level of investment in, research, development, and commercialization activities relating to our product and product candidates, which may change from time to time;

- the timing of receipt of approvals or clearances for our product candidates from regulatory authorities in the United States or internationally;
- the timing and status of enrollment for our clinical trials;
- coverage and reimbursement policies with respect to our product and product candidates, including the degree to which treatments using our products are covered and receive adequate reimbursement from third-party payors, and potential future drugs or devices that compete with our products;
- the costs of manufacturing our product, as well as building out our supply chain, which may vary depending on the quantity of production and which will vary significantly depending upon the terms of our agreements with manufacturers;
- expenditures that we may incur to acquire, develop or commercialize additional product candidates and technologies;
- the level of demand for our product and any product candidates, if approved or cleared, which may vary significantly over time;
- litigation, including patent, employment, securities class action, stockholder derivative, general commercial, and other lawsuits;
- future accounting pronouncements or changes in our accounting policies; and
- the timing and success or failure of nonclinical studies and clinical trials for our product candidates or competing product candidates, or any other change in the competitive landscape of our industry, including consolidation among our competitors or partners.

The cumulative effects of these factors could result in large fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results on a period-to-period basis may not be meaningful. Investors should not rely on our past results as an indication of our future performance.

This variability and unpredictability could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our revenue or operating results fall below the expectations of analysts or investors or below any forecasts we may provide to the market, or if the forecasts we provide to the market are below the expectations of analysts or investors, the price of our common stock could decline substantially. Such a stock price decline could occur even when we have met our previously publicly stated revenue or earnings guidance.

Because we operate in a highly competitive market, we can expect to face competition from large, well-established manufacturers of medical technologies, devices and similar products; we may not be able to compete effectively against companies with significantly more resources.

The medical technology, medical device, biotechnology, and pharmaceutical industries are characterized by intense and dynamic competition to develop new technologies and proprietary therapies. We face competition from a number of sources, such as pharmaceutical companies, medical device companies, generic drug companies, biotechnology companies, and academic and research institutions. We may find ourselves in competition with companies that have competitive advantages over us, such as:

- significantly greater name recognition;
- established relationships with healthcare professionals, customers, and third-party payers;
- competitive products with greater efficacy or better safety profiles;
- established distribution networks;
- additional lines of products and the ability to offer rebates, higher discounts, or incentives to gain a competitive advantage;

- greater experience in obtaining patents and regulatory approvals for product candidates;
- greater experience conducting new product research and development, manufacturing therapies, conducting clinical trials, obtaining regulatory approval for products, and marketing approved products; and
- greater financial and human resources for product development, sales and marketing.

We may also face increased competition in the future as new companies enter our markets and as scientific developments surrounding electro-signaling therapeutics continue to accelerate. While we will seek to expand our technological capabilities to remain competitive, research and development by others may render our technology or product candidates obsolete or noncompetitive or result in treatments or cures superior to any therapy developed by us. In addition, certain of our product candidates may compete with other dermatological products, including over the counter (OTC) treatments, for a share of some patients' discretionary budgets and for physicians' attention within their clinical practices. Even if a generic product or an OTC product is less effective than our product candidates, a less effective generic or OTC product may be more quickly adopted by physicians and patients than our competing product candidates based upon cost or convenience. As a result, we may not be able to compete effectively against current and potential future competitors or their devices and products.

We may rely on third parties for our sales, marketing, manufacturing, and/or distribution activities, and these third parties may not perform satisfactorily.

To be able to commercialize our products and planned products, we may elect to internally develop aspects of sales, marketing, large-scale manufacturing, or distribution, or we may elect to use third parties with respect to one or more of these functions. Our reliance on these third parties may reduce our control over these functions; however, reliance on third parties does not relieve us of our responsibility to ensure compliance with all required legal, regulatory, and scientific standards. These third parties may also be adversely impacted by COVID-19 which could affect their ability to perform satisfactorily. Any failure of these third parties to perform satisfactorily and in compliance with relevant laws and regulations could lead to delays in the development of our products or planned products, including delays in our clinical trials, or failure to obtain necessary regulatory approvals, or failure to successfully commercialize our products or other future products. Some of these events could be the basis for FDA or other regulatory action, including injunction, recall, seizure, or total or partial suspension of production.

We have not yet commenced revenue-producing operations and may be unsuccessful in earning significant revenues. We believe that developing the commercialization aspects of a company will take a substantial amount of capital and commitment of time and effort. We may seek development and marketing partners and license our technology to others in order to avoid our having to provide the marketing, manufacturing, and distribution capabilities within our organization. There can be no assurance that we will find any development and marketing partners or companies that are interested in licensing our technology. If we are unable to establish and maintain adequate sales, marketing, manufacturing, and distribution capabilities, independently or with others, we will not be able to generate product revenue, and may not become profitable.

If we lose key management personnel, our ability to identify, develop and commercialize new or next generation product candidates will be impaired, could result in loss of markets or market share and could make us less competitive.

We are highly dependent upon the principal members of our management team, including our Chief Executive Officer, Darrin Uecker, and members of our finance, sales, marketing, scientific, and engineering teams. These persons have significant experience and knowledge with sub-microsecond pulsed electric fields and more broadly in aesthetics, dermatology, life sciences, and medical technologies. The loss of any team member could impair our ability to design, identify, and develop new intellectual property and new scientific or product ideas. The loss of a key employee, the failure of a key employee to perform in his or her current position, or our inability to attract and retain skilled employees could result in our inability to continue to grow our business or to implement our business strategy. We compete for qualified management and scientific personnel with other life science companies, academic institutions, and research institutions. Our employees could leave our company with little or no prior notice and may be free to work for a competitor. If one or more of our senior executives or other key personnel were unable or unwilling to continue in their present positions, we may not be able to replace them easily or at all, and other senior management may be required to divert attention from other aspects of the business. In addition, we do not have "key person" life insurance policies covering any member of our management team or other key personnel. The loss of any of these individuals or any inability to attract or retain qualified personnel, including scientists, engineers, and others, could prevent us from pursuing collaborations and materially and adversely affect our product development and introductions, business growth prospects, results of operations, and financial condition.

There is a limited talent pool of experienced professionals in our industry. If we are not able to retain and recruit personnel with the requisite technical skills, we may be unable to successfully execute our business strategy.

The specialized nature of our industry results in an inherent scarcity of experienced personnel in the field. Our future success depends upon our ability to attract and retain highly skilled personnel, including scientific, technical, commercial, business, regulatory, and administrative personnel, necessary to support our anticipated growth, develop our business and perform certain contractual obligations. Given the scarcity of professionals with the scientific knowledge we require and the intense competition that exists for qualified personnel among life science businesses, we may not succeed in attracting or retaining the personnel we require to continue and grow our operations.

Rapidly changing technology in life sciences could make the products we are developing obsolete.

The life sciences industries are characterized by rapid and significant technological changes, frequent new product introductions and enhancements, and evolving industry standards. Our future success will depend on our ability to continually develop and then improve the products that we design and to develop and introduce new products that address the evolving needs of our customers on a timely and cost-effective basis. Also, we will need to pursue new market opportunities that develop as a result of technological and scientific advances. These new market opportunities may be outside the scope of our proven expertise or in areas which have unproven market demand. Any new products developed by us may not be accepted in the intended markets. Our inability to gain market acceptance of new products could harm our future operating results.

If we are unable to manage the anticipated growth of our business, our future revenue and operating results may be harmed.

We have experienced rapid growth in our business. Recent and future growth imposes significant added responsibilities on management, including the need to identify, recruit, train, and integrate additional employees. Rapid expansion in personnel could mean that fewer experienced people carry out our research and development activities, manufacture, market, and sell CellFX Systems and NPS therapies and treatments, which could result in inefficiencies and unanticipated costs, reduced quality, and disruptions to our operations. In addition, rapid and significant growth may strain our administrative and operational infrastructure, and the failure to continue to upgrade our technical, administrative, operating, and financial control systems, or the occurrence of other unexpected expansion difficulties, could have a material adverse effect on our business, financial condition and results of operations, and our ability to timely execute our business plan. If we are unable to manage our growth effectively, it may be difficult for us to execute our business strategy and our business could be harmed.

We are subject to laws and regulations relating to personally identifiable health information, and other sensitive information. Security breaches, loss of data and other disruptions to us or our third-party service providers could compromise sensitive information related to our business or prevent us from accessing critical information and expose us to liability, which could adversely affect our business and our reputation.

In the ordinary course of our business, both we and our third-party service providers may collect and store sensitive data, including legally protected health information, personally identifiable information about our patients, information related to our trials, intellectual property, and our proprietary business and financial information. We manage and maintain our applications and data using a combination of on-site and vendor-owned systems. We face a number of risks related to our protection of, and our service providers' protection of, this critical information, including loss of access to data, data corruption, unauthorized disclosure of data, and unauthorized access of data, as well as risks associated with our ability to identify and audit such events.

Although we take measures to protect sensitive information from unauthorized access or disclosure, our information technology and infrastructure, or those of our vendors, may be vulnerable to attacks by hackers or viruses or otherwise breached due to employee error, malfeasance or other activities. While we believe we have not experienced any such attack or breach, both we and our vendors may be unable to anticipate attacks, to implement adequate preventative or mitigation measures, to identify any attacks or incidents on a timely basis, or to remediate or otherwise address any attacks or incidents in a timely manner. If any such attack or other incident were to occur, our systems and networks would be compromised and the information we store on those systems and networks could be accessed by unauthorized parties, publicly disclosed, lost, or stolen. Any such access, disclosure or other loss of information could result in a loss of intellectual property protection, legal claims or proceedings, liability under laws that protect the privacy of personal information, such as the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA), as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH), and the California Consumer Privacy Act of 2018 (CCPA), which was enacted in June 2018 and became operative on January 1, 2020, or regulatory penalties, and could require substantial efforts to remediate and otherwise respond to the incident. The CCPA requires covered companies to, among other things, make certain enhanced disclosures related to California residents regarding our use or disclosure of their personal information, allow California residents to opt-out of certain uses and disclosures of their personal information without penalty, provide Californians with other choices related to personal data in our possession, and obtain opt-in consent before engaging in certain uses of personal information relating to Californians under the age of 16. The California Attorney General may seek substantial monetary penalties and injunctive relief in the event of our non-compliance with the CCPA. The CCPA also allows for private lawsuits from Californians in the event of certain data breaches. Certain aspects of the CCPA and its interpretation remain uncertain, and we may need to modify our policies or practices in an effort to comply with it. Moreover, a new privacy law, the California Privacy Rights Act (CPRA) was recently approved by California voters, which significantly modifies the CCPA, resulting in further uncertainty and requiring us to incur additional costs and expenses in an effort to comply.

Unauthorized access, loss or dissemination of data could also disrupt our operations, including our ability to process tests, provide test results, provide services, conduct research and development activities, collect, process and prepare company financial information, provide information about our product candidates and manage the administrative aspects of our business and could damage our reputation, any of which could adversely affect our business. We cannot be certain that our insurance coverage will be adequate for data handling or data security liabilities actually incurred, that insurance will continue to be available to us on economically reasonable terms, or at all, or that any future claim will not be excluded or otherwise be denied coverage by any insurer. The successful assertion of one or more claims against us that exceed available insurance coverage, or the occurrence of changes in our insurance policies, including premium increases or the imposition of large deductible or co-insurance requirements, could have a material adverse effect on our business, including our financial condition, operating results and reputation.

In addition, the interpretation and application of federal and state consumer, health-related and data protection laws in the United States are often uncertain, contradictory and in flux. It is possible that these laws may be interpreted and applied in a manner that is, or alleged to be, inconsistent with our practices. If so, this could result in regulatory investigations and enforcement actions, private litigation, claims for damages, and government-imposed fines or orders requiring that we change our practices, any of which could adversely affect our business. Complying with these various laws could cause us to incur substantial costs or require us to change our business practices, systems and compliance procedures in a manner adverse to our business.

Product liability lawsuits against us could cause us to incur substantial liabilities and limit commercialization of our product or any future products that we may develop.

We face an inherent risk of product liability exposure related to the sale of our product and the future sale of planned products and the use of these in human clinical studies. For example, we may be sued if our product or any of our product candidates, including any that are developed in combination therapies, allegedly causes injury, or is found to be otherwise unsuitable during product testing, manufacturing, marketing, or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability, or a breach of warranties. We may also be subject to liability for a misunderstanding of, or inappropriate reliance upon, the information we provide. If we cannot successfully defend ourselves against claims that our product or planned products caused injuries, we may incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in, among other things:

- decreased demand for our product or any planned products that we may develop;
- injury to our reputation and significant negative media attention;
-

withdrawal of patients from our clinical studies or cancellation of studies;

- significant costs to defend the related litigation and distraction to our management team;
- substantial monetary awards to patients;
- loss of revenue; and
- the inability to commercialize any future products that we may develop.

For example, for our clinical trials in the field of oncology, patients with the types and stages of cancer targeted by our NPS technology may already be in severe and advanced stages of disease, may have worsened conditions despite traditional therapies, may not be surgical candidates, and/or may have both known and unknown significant pre-existing and potentially life-threatening conditions. During the course of treatment, patients may suffer adverse events, including death, for reasons that may be related to our CellFX System or our NPS technology. Such events could subject us to costly litigation, require us to pay substantial amounts of money to injured patients, delay, negatively impact, or end our opportunity to receive or maintain regulatory approval to market those products, or require us to suspend or abandon our commercialization efforts. Even in a circumstance in which we do not believe that an adverse event is related to our product, the investigation into the circumstance may be time-consuming or inconclusive. These investigations may interrupt our sales efforts, delay our regulatory approval processes, or impact and limit the type of regulatory approvals our products could receive or maintain. As a result of these factors, a product liability claim, even if successfully defended, could harm our business.

We currently maintain product liability insurance coverage, which may not be adequate to cover all liabilities that we may incur. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

Our ability to utilize our net operating loss carryforwards and certain other tax attributes may be limited.

We have incurred net losses since our inception and anticipate that we may continue to incur significant losses for the foreseeable future. If not utilized, some of our federal and state net operating losses (NOLs) carryforwards will begin to expire in various years beginning after 2034. Under the Internal Revenue Code of 1986, as amended, or the Code, and certain similar state tax provisions, we are generally allowed to carry forward our NOLs from a prior taxable year to offset our future taxable income, if any, until such NOLs are used or expire, subject to certain limitations. The same is true of other unused tax attributes, such as tax credits.

In addition, under Section 382 of the Code, a corporation that undergoes an “ownership change” is subject to limitations on its ability to utilize its pre-change NOLs to offset future taxable income. We believe that we have had one or more ownership changes, and, as a result, a portion of our existing NOLs may be subject to limitation. Future changes in our stock ownership could result in additional limitations. We may not be able to utilize a material portion of our NOLs even if we attain profitability.

We have a substantial amount of goodwill and intangible assets which over time may have to be written down as we make the required periodic assessments as to their value as reflected in our financial statements.

A significant portion of our total assets are comprised of goodwill and intangibles that arose from our 2014 business acquisitions. We review goodwill for impairment at least annually or whenever changes in circumstances indicate that the carrying value of the goodwill may not be recoverable. We also review our intangible assets for impairment at each fiscal year end or when events or changes in circumstances indicate the carrying value of these assets may exceed their current fair values. If we take an impairment charge for either goodwill or intangible assets, the overall assets will be reduced. Such an impairment charge may result in a change in the perceived value of the company and ultimately may be reflected as a reduction in the market price of our securities. Additionally, an impairment charge may also adversely influence our ability to raise capital in the future.

Risks Related to Product Development

Clinical development involves a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results.

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure or delay can occur at any time during the clinical trial process. For example, success in nonclinical studies and early feasibility clinical studies does not ensure that the expanded clinical trials needed to support regulatory submissions will be successful. Setbacks can be caused by, among other things, nonclinical findings made while clinical trials are underway, safety or efficacy observations made in clinical trials, including previously unreported adverse events, or post-approval observations. Even if our clinical trials are completed, the results may not be sufficient to obtain regulatory approval or clearance for our product candidates.

Interim "top-line" and preliminary results from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publish interim top-line or preliminary results from our clinical trials. Interim results from clinical trials that we may announce are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Preliminary or top-line results also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, interim and preliminary data should be viewed with caution until the final data are available. Differences between preliminary or interim data and final data could significantly harm our business prospects and may cause the trading price of our common stock to fluctuate significantly.

If we fail to maintain necessary regulatory clearance for our product, or if clearances or approvals for future devices and indications are delayed or not issued, our commercial operations would be harmed.

Our product candidates under development are medical devices that are subject to extensive regulation by the FDA in the United States and by regulatory agencies in other countries where we do business. Government regulations specific to medical devices are wide-ranging and govern, among other things:

- device design, development and manufacture;
- laboratory, pre-clinical and clinical testing, labeling, packaging, and storage;
- premarketing clearance or approval;
- record keeping;
- device marketing, promotion and advertising, sales and distribution; and
- post-marketing surveillance, including reporting of deaths and serious injuries and recalls and correction and removals.

Before a new medical device, or a new intended use for an existing device, can be marketed in the United States, the device's manufacturer must first submit and receive either 510(k) clearance or Premarket Approval (PMA) from the FDA, unless an exemption applies. In the 510(k) clearance process, the FDA will determine that a proposed device is "substantially equivalent" to a device legally on the market, known as a "predicate" device, with respect to intended use, technology and safety and effectiveness, in order to clear the proposed device for marketing. Clinical data is sometimes required to support substantial equivalence. The PMA pathway requires an applicant to demonstrate reasonable safety and effectiveness of the device based on extensive data, including, but not limited to, technical, pre-clinical, clinical trial, manufacturing, and labeling data. The PMA process is typically required for devices that are deemed to pose the greatest risk, such as life-sustaining, life-supporting, or implantable devices. Products that are approved through a PMA application generally need FDA approval before they can be modified. Similarly, some modifications made to products cleared through a 510(k) may require a new 510(k). Either process can be expensive, lengthy and unpredictable.

In February 2021, we received a 510(k) clearance from the U.S. FDA for our CellFX System for dermatologic procedures requiring ablation and resurfacing of the skin. Following this general dermatologic indication, we plan to pursue specific indications for the CellFX System, starting with an indication for the treatment of SH lesions. This will require an additional 510(k) submission, as will each subsequent indication, and will likely be based on comparative clinical data.

However, the failure to obtain further 510(k) clearances may add significant time and expense to our regulatory clearance process, may delay our ability to generate revenue, and may have a negative impact on our stock price. We may not be able to obtain the necessary clearances or approvals necessary to market our CellFX System for specific indications or such approvals or clearances may be unduly delayed, which could harm our business. If the FDA rejects our 510(k) submissions for specific indications, we may be required to obtain FDA approval through the de novo pathway, which will require additional time and resources, including the need to conduct more clinical studies to demonstrate safety and effectiveness of our candidate device.

The FDA may not approve or clear our 510(k), de novo, or PMA applications on a timely basis or at all. Such delays or refusals could have a material adverse effect on our business operations and financial condition. The FDA may also change its clearance and approval policies, adopt additional regulations or revise existing regulations, or take other action which may prevent or delay approval or clearance of our products under development. Any of these actions could have a material adverse effect on our business operations and financial condition.

The FDA and the U.S. Federal Trade Commission (FTC) also regulate the advertising and promotion of our devices to ensure that the claims we make are consistent with our regulatory clearances or approvals, that there are adequate and reasonable data to substantiate the claims and that our promotional labeling and advertising is neither false nor misleading in any respect. If the FDA or the FTC determines that any of our advertising or promotional claims are misleading, not substantiated or not permissible, we may be subject to enforcement actions, including FDA warning letters, and we may be required to revise our promotional claims and make other corrections or restitutions.

FDA and state authorities have broad enforcement powers. Our failure to comply with applicable regulatory requirements could result in enforcement action by the FDA or state agencies, which may include any of the following sanctions, among others:

- adverse publicity, warning letters, fines, injunctions, consent decrees, and civil penalties;
- repair, replacement, refunds, recall, or seizure of our devices;
- operating restrictions, partial suspension, or total shutdown of production;
- refusing our requests for 510(k) clearance or premarket approval of new devices, new intended uses or modifications to existing devices;
- withdrawing 510(k) clearance or premarket approvals that have already been granted; and
- criminal prosecution.

If any of these events were to occur, our business and financial condition would be harmed.

The mechanism of action of NPS technology platform has not been fully determined or validated.

The exact mechanism(s) of action(s) of the NPS technology platform is not fully understood, and data is still being gathered regarding its use. Furthermore, there are only a relatively small number of scientists and researchers who can be considered experts in the use of this emerging technology. Insofar as potential regulators, partners or investors value a clear understanding of a technology's mechanism of action, this limitation could make it more challenging for us to obtain requisite regulatory approvals, investments or a partnership on favorable terms as a result.

Our product and any future product candidates may cause serious adverse side effects or have other properties that could delay or prevent their regulatory approval, limit their commercial desirability or result in significant negative consequences.

The risk of failure of clinical development is high. For example, the vast majority of our in vivo data has been a result of animal testing, and we have only completed a limited number of feasibility studies in humans. Undesirable side effects caused by our CellFX System, NPS pulses, or any of our planned future products could cause us or regulatory authorities to interrupt, delay or halt clinical trials or to revoke previously granted regulatory approvals. Undesirable side effects could also result in more restrictive labeling requirements or the delay or denial of regulatory approval of planned future products by the FDA or other comparable foreign regulatory authority.

Additionally, if we or others identify undesirable side effects caused by our CellFX System, a number of potentially significant negative consequences could result, including:

- we may be forced to recall such product and suspend the marketing of such product;
- regulatory authorities may withdraw their approvals of such product;
- regulatory authorities may require additional warnings on the label and/or narrow the indication that could diminish the usage or otherwise limit the commercial success of such product;
- the FDA or other regulatory authorities may issue safety alerts, “Dear Healthcare Provider” letters, press releases, or other communications containing warnings about such product;
- the FDA may restrict distribution of our product and impose burdensome implementation requirements on us;
- we may be required to change the way the product is administered or conduct additional clinical trials;
- we could be sued and held liable for harm caused to subjects or patients;
- we may be subject to litigation or product liability claims; and
- our reputation could suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the CellFX System or of any future particular planned product, if approved.

Our business is dependent upon physicians adopting our CellFX System and NPS technology, and if we fail to obtain broad adoption, our business would be adversely affected.

Our success depends on our ability to educate physicians regarding the benefits of CellFX procedures over existing treatment modalities and to persuade them to prescribe CellFX procedures for their patients. We do not know if the CellFX System or NPS technology will be successful over the long term, and market acceptance may be hindered if physicians are not presented with compelling data demonstrating the efficacy and safety of our products compared to alternative treatments. Any studies we, or third parties, may conduct comparing our CellFX System or NPS technology with alternative treatments may be expensive, time consuming or may not yield positive results. Additionally, adoption will be directly influenced by a number of financial factors, including the ability of providers to attract cash payments from patients or to obtain sufficient reimbursement from third-party commercial payors and from the Centers for Medicare & Medicaid Services (CMS) for the professional services they provide in administering CellFX procedures. The efficacy, safety, performance, and cost-effectiveness of our CellFX System, NPS technology, or other potential products based on NPS technology, on a stand-alone basis and relative to competing services, will determine the availability and level of reimbursement received by us and providers. If physicians do not adopt and prescribe our CellFX System or future products using our NPS technology, we may never become profitable.

We may find it difficult to enroll patients in our clinical trials. If we cannot enroll a sufficient number of eligible patients to participate in the clinical trials, we may not be able to initiate or continue clinical trials, which could delay or prevent development of our product candidates.

Identifying and qualifying patients to participate in clinical trials of our product candidates is critical to our success. The timing of our clinical trials depends on the speed at which we can recruit patients to participate in testing our product candidates as well as completion of required follow-up periods. In general, if patients are unwilling to participate in our trials because of negative publicity from adverse events in the health care industry or for other reasons, including competitive clinical trials for similar patient populations, the timeline for recruiting patients, conducting trials and obtaining regulatory approval or clearance of planned products may be delayed. If there are delays in accumulating the required patients and patient data, there may be delays in completing the trial. Further, if any of our clinical trial sites fail to comply with required good clinical practices, we may be unable to use the data gathered at those sites. Also, if our clinical investigators fail to carry out their contractual duties or regulatory obligations or fail to meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to their failure to adhere to our clinical protocols or for other reasons, our clinical trials may be delayed, suspended, or terminated. These delays could result in increased costs, delays in advancing our product development, delays in testing the effectiveness of our technology or termination of the clinical trials altogether, and delays in obtaining regulatory authorization for our products.

Laboratory conditions differ from commercial conditions and field conditions, and the safety and effectiveness of our product candidates may depend on the technique of the user.

Observations and developments that may be achievable under laboratory circumstances may not be able to be replicated in broader research and development phases, in commercial settings, or in the use of any of the product candidates in the field. Furthermore, CellFX procedures will be administered by healthcare professionals and will require a degree of training and practice to administer correctly. Treatment results achieved in the laboratory or in clinical trials conducted by us or by other investigators may not be representative of the results actually encountered during commercial use of our products due to variability in administration technique. The training and skills of investigators in our clinical trials may not be representative of the training and skills of future product users, which could negatively affect treatment results. In addition, there may be a selection bias in the patients and/or sites of administration chosen for any clinical trials that would positively affect treatment results that may not be representative or predictive of real-world experience with our products, including the CellFX System.

Issues with our firmware and software may negatively affect the function of our devices.

The safety and effectiveness of CellFX procedures and therapies may depend, in part, on the function of firmware run by the microprocessors embedded in the device and associated software. This firmware and software is proprietary to us. While we have made efforts to test the firmware and software extensively, it is potentially subject to malfunction which in turn may harm patients. Further, our proprietary firmware and software may be vulnerable to physical break-ins, hackers, improper employee or contractor access, computer viruses, programming errors, data breaches, or similar problems. Any of these might result in harm to patients or the unauthorized release of confidential medical, business or other information belonging to us or to other persons.

We may encounter manufacturing problems or delays that could result in lost revenue. Additionally, we currently rely on third-party suppliers for critical materials needed to manufacture our CellFX System and related applicators. Any problems experienced by these suppliers could result in a delay or interruption of their supply to us and, as a result, we may face delays in the development and commercialization of planned products.

We are in the process of commencing commercial-scale manufacturing of our product, and we currently rely upon third-party suppliers to manufacture and supply components for our CellFX System. We perform final assembly of our devices at our facility in California. We believe we have an adequate inventory of materials and manufacturing capacity to support all our commercial launch activities. However, if demand for our product increases significantly, we will need to either expand our manufacturing capabilities or outsource to other manufacturers. The manufacture of our CellFX components in compliance with the FDA's regulations requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of medical device products often encounter difficulties in production, including difficulties with production costs and yields, quality control, quality assurance testing, shortages of qualified personnel, as well as compliance with applicable regulations, both foreign and domestic.

We do not control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with applicable regulatory requirements, and if our contract manufacturers cannot successfully manufacture the components needed for our product in a manner that conforms to our specifications and these strict regulatory requirements, we may not be able to rely on their manufacturing facilities for the manufacture of our product. In addition, we have limited control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority finds these facilities inadequate for the manufacture of our components or if such facilities are subject to enforcement action in the future or are otherwise inadequate with respect to complying with applicable regulatory requirements, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop and market our product or to obtain regulatory approval or clearance for our product candidates.

We currently purchase components for our CellFX System under purchase orders and do not have long-term contracts with most of the suppliers of these materials. If suppliers were to delay or stop producing our components, or if the prices they charge us were to increase significantly, or if they elected not to sell to us, we would need to identify other suppliers and we may not be able to secure alternative suppliers on favorable terms, or at all. Also, any number of our suppliers may be adversely impacted by COVID-19 which could affect their ability to perform satisfactorily. Any failure of these suppliers to perform satisfactorily could adversely impact our business and results of operations and we may experience delays in manufacturing of our devices while finding another acceptable supplier.

We may not become commercially viable if our ultimate commercialized products or related treatments fail to obtain an adequate level of reimbursement by Medicare and other third-party payers.

We believe that the commercial viability of our CellFX System and any potential devices and products and related treatments, and therefore our commercial success as a company, may be affected by the availability of government reimbursement and medical insurance coverage and reimbursement for newly approved medical therapies, technologies, and devices. Insurance coverage and reimbursement are not assured. It typically takes a period of use in the marketplace before coverage and reimbursement are granted, if it is granted at all. In the United States and in many other jurisdictions, physicians and other healthcare providers generally rely on insurance coverage and reimbursement for their revenues, therefore this is an important factor in the overall commercialization plans of a proposed product and whether it will be accepted for use in the marketplace. Without insurance coverage and reimbursement for our planned products, we would expect to earn only diminished revenues, if any revenues are earned.

Medicare, Medicaid, health maintenance organizations, and other third-party payers are increasingly attempting to contain healthcare costs by limiting both the scope of coverage and the level of reimbursement of new medical technologies and products. As a result, they may not cover or provide adequate payment for the use of our CellFX System or planned products in development. In order to obtain satisfactory reimbursement arrangements, we may have to agree to reduce our fee or sales price below what we currently expect to charge customers, which could adversely affect our profit margins. Moreover, each plan may separately require us to provide scientific and clinical support for the use of our products and, as a result, the coverage determination process is often a time-consuming and costly process with no assurance that coverage and adequate reimbursement will be applied consistently or obtained at all. Even if Medicare and other third-party payers decide to cover treatments involving our CellFX System and our proposed devices and products, we cannot be certain that the reimbursement levels will be adequate. Accordingly, even if these products are approved for commercial sale, unless government and other third-party payers provide adequate coverage and reimbursement for our devices and products, some physicians may be discouraged from using them, and our sales would suffer.

Medicare reimburses for medical technologies and products in a variety of ways, depending on where and how the item is used. However, Medicare only provides reimbursement if CMS determines that the item should be covered and that the use of the device or product is consistent with the coverage criteria. A coverage determination can be made at the local level by the Medicare administrative contractor, a private contractor that processes and pays claims on behalf of CMS for the geographic area where the services were rendered, or at the national level by CMS through a national coverage determination. There are statutory provisions intended to facilitate coverage determinations for new technologies, but it is unclear how these new provisions will be implemented, and it is not possible to indicate how they might apply to any of our proposed devices and products, as they are still in the development stages. Coverage presupposes that the technology, device, or product has been cleared or approved by the FDA and further, that the coverage will be consistent with the approved intended uses of the device or product as approved or cleared by the FDA, but coverage can be narrower. A coverage determination may be so limited that relatively few patients will qualify for a covered use of a device or product.

Obtaining a coverage determination, whether local or national, is a time-consuming, expensive and highly uncertain proposition, especially for a new technology, and inconsistent local determinations are possible. On average, Medicare coverage determinations for medical devices and products lag behind FDA approval or clearance. The Medicare statutory framework is also subject to administrative rulings, interpretations and discretion that affect the amount and timing of reimbursement made under Medicare. Medicaid coverage determinations and reimbursement levels are determined on a state-by-state basis, because Medicaid, unlike Medicare, is administered by the states under a state plan filed with the Secretary of the U.S. Department of Health and Human Services (HHS). Medicaid generally reimburses at lower levels than Medicare. Moreover, Medicaid programs and private insurers are frequently influenced by Medicare coverage determinations.

We work with outside scientists and their institutions in developing our product and product candidates. These scientists may have other commitments or conflicts of interest, which could limit our access to their expertise, harm our ability to leverage our discovery platforms, or negatively impact our clinical trials.

We work with scientific advisors and collaborators at academic research institutions in connection with our product development efforts. These scientists and collaborators are not our employees, but they serve as either independent contractors or researchers under research agreements that we have with their sponsoring clinic, academic institution or research institution. These scientists and collaborators may have other commitments limiting their availability to us. Although our scientific advisors generally agree not to do competing work, if an actual or potential conflict of interest between their work for us and their work for another entity arises, we may lose their services. It is also possible that some of our valuable proprietary knowledge may become publicly known through these scientific advisors if they breach their confidentiality agreements with us, which would cause competitive harm to our business. To the extent these scientists and collaborators, including those assisting us with our clinical trials, may receive cash or equity compensation in connection with such services from time to time, these relationships and any related compensation may result in perceived or actual conflicts of interest, or cause a regulatory authority to conclude that the financial relationship may have affected the interpretation of the trial, such that the integrity of the data generated by them or by their institutions may be questioned and the utility of the data itself may be jeopardized, which could result in the delay or rejection of any marketing application we submit.

Risks Related to Intellectual Property

If we are unable to protect our intellectual property, then our financial condition, results of operations and the value of our technology and products could be adversely affected.

Patents and other proprietary rights are essential to our business and our ability to compete effectively with other companies is dependent upon the proprietary nature of our technologies. We also rely upon trade secrets, know-how, continuing technological innovations, and licensing opportunities to develop, maintain and strengthen our competitive position. We seek to protect these, in part, through confidentiality agreements with certain employees, consultants and other parties. Our success will depend in part on the ability of our licensors and us to obtain, to maintain (including making periodic filings and payments) and to enforce patent protection for the licensed intellectual property, in particular, those patents to which we have secured rights. We may not successfully prosecute or continue to prosecute the patent applications which we have licensed. Even if patents are issued in respect of these patent applications, we may fail to maintain these patents or may determine not to pursue litigation against entities that are infringing upon these patents. Without adequate protection for the intellectual property that we own or license, other companies might be able to offer substantially identical products for sale, which could unfavorably affect our competitive business position and harm our business prospects. Even if issued, patents may be challenged, invalidated, or circumvented, which could limit our ability to stop competitors from marketing similar products or limit the length of term of patent protection that we may have for our products.

Litigation or third-party claims of intellectual property infringement or challenges to the validity of our patents would require us to use resources to protect our technology and may prevent or delay our development, regulatory approval or commercialization of our product candidates.

If we are the target of claims by any third party asserting that our products or intellectual property infringe upon the rights of others, we may be forced to incur substantial expenses or divert substantial employee resources from our business. If successful, such claims could result in our having to pay substantial damages or could prevent us from developing one or more product candidates. Further, if a patent infringement suit were brought against us or our collaborators, we or they could be forced to stop or delay research, development, manufacturing, or sales of the product or product candidate that is the subject of the suit.

If we, or our collaborators, experience patent infringement claims, or if we elect to avoid potential claims others may be able to assert, we or our collaborators may choose to seek, or be required to seek, a license from the third party and would most likely be required to pay license fees or royalties or both. These licenses may not be available on acceptable terms, or at all. Even if we or our collaborators were able to obtain a license, the rights may be nonexclusive, which would give our competitors access to the same intellectual property. Ultimately, we could be prevented from commercializing a product, or be forced to cease some aspect of our business operations if, as a result of actual or threatened patent infringement claims, we or our collaborators are unable to enter into licenses on acceptable terms. This could harm our business significantly. The cost to us of any litigation or other proceeding, regardless of its merit, even if resolved in our favor, could be substantial. Some of our competitors may be able to bear the costs of such litigation or proceedings more effectively than we can because of their having greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace. Intellectual property litigation and other proceedings may, regardless of their merit, also absorb significant management time and employee resources.

Our intellectual property rights will not necessarily provide us with competitive advantages.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business, or permit us to maintain our competitive advantage. The following examples are illustrative:

- others may be able to make products that are similar to our product candidates but that are not covered by the claims of the patents that we own or have exclusively licensed;
- others may independently develop similar or alternative technologies without infringing on our intellectual property rights;
- issued patents that we own or have exclusively licensed may not provide us with any competitive advantages, or may be held invalid or unenforceable, as a result of legal challenges by our competitors;
- we may obtain patents for certain products many years before we obtain marketing approval for products utilizing such patents, and because patents have a limited life, which may begin to run prior to the commercial sale of the related product, the commercial value of our patents may be limited;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may fail to develop additional proprietary technologies that are patentable;
- the laws of certain foreign countries may not protect our intellectual property rights to the same extent as the laws of the United States, or we may fail to apply for or obtain adequate intellectual property protection in all the jurisdictions in which we operate; and
- the patents of others may have an adverse effect on our business, for example by preventing us from marketing one or more of our product candidates for one or more indications.

Any of the aforementioned threats to our competitive advantage could harm our business.

If we are unable to protect the confidentiality of our proprietary information and know-how, the value of our technology and products could be adversely affected.

In addition to patented technology, we rely upon, among other things, unpatented proprietary technology, processes, trade secrets, and know-how. Any involuntary disclosure to, or misappropriation by, third parties of our confidential or proprietary information could enable competitors to duplicate or surpass our technological achievements, potentially eroding our competitive position in our market. We seek to protect confidential and proprietary information in part by confidentiality agreements with our employees, consultants and third parties. While we require all of our employees, consultants, advisors, and any third parties who have access to our proprietary know-how, information and technology to enter into confidentiality agreements, we cannot be certain that this know-how, information and technology will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. These confidentiality agreements may be terminated or breached, and we may not have adequate remedies for any such termination or breach. Furthermore, these agreements may not provide meaningful protection for our trade secrets and know-how in the event of unauthorized use or disclosure.

If we are unable to protect the intellectual property used in our products, others may be able to copy our innovations which may impair our ability to compete effectively in our markets.

The strength of our patents involves complex legal and scientific questions and can be uncertain. Our patents or patent applications may be challenged or our patent applications may fail to result in issued patents and our existing or future patents may be too narrow to prevent third-parties from developing or designing around our intellectual property and in that event we may lose competitive advantage and our business may suffer.

We may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States. can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the U.S. or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our current or future product candidates, if any, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

We have not yet registered some of our trademarks in all of our potential markets, and failure to secure those registrations could adversely affect our business. If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

Our registered or unregistered trademarks or trade names may be challenged, infringed, circumvented, declared generic, or conflict with third-party rights. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition by potential partners or customers in our markets of interest. Additionally, if we apply to register our trademarks in all of our potential markets, our applications may not be allowed for registration, and our registered trademarks may not be maintained or enforced. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. If we do not secure registrations for our trademarks, we may encounter more difficulty in enforcing them against third parties than we otherwise would. In such cases, over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then our marketing abilities may be impacted.

Risks Related to Government Regulation

We are subject to stringent domestic and foreign regulation. Any unfavorable regulatory action or adverse change in law may materially and adversely affect our future financial condition and business operations and prospects.

Our CellFX System and any other potential devices and products, further development activities and manufacturing and distribution, once developed and determined, are, and will continue to be, subject to extensive, rigorous, and ongoing regulation by numerous government agencies, including the FDA and similar foreign regulatory authorities. To varying degrees, each of these agencies monitors and enforces our compliance with laws and regulations governing the development, testing, manufacturing, labeling, marketing, distribution, and the safety and effectiveness of our medical technology. The process of obtaining and maintaining marketing approval or clearance from the FDA and similar foreign regulatory authorities for new devices and products, or for enhancements, expansion of the indications or modifications to existing products, could:

- take a significant indeterminate amount of time;
- require the expenditure of substantial resources;
- involve rigorous pre-clinical and clinical testing, and possibly post-market surveillance;
- involve modifications, repairs or replacements of our products;
- require design changes of our products;
- result in limitations on the indicated uses of our products; and
- result in our never being granted the regulatory approval or clearance we seek.

If we experience any of these occurrences, our operations may suffer, we might experience harm to our competitive standing and result in further losses that adversely affect our financial condition.

We are subject to and will have ongoing responsibilities under FDA and international regulations, both before and after a product is approved or cleared and commercially released. Compliance with applicable regulatory requirements is subject to continual review and is monitored rigorously through periodic inspections. If an inspection were to conclude that we are not in compliance with applicable laws or regulations, or that any of our devices are ineffective or pose an unreasonable health risk, the FDA or similar foreign regulatory authorities could ban such devices or products, detain or seize such devices or products, order a recall, repair, replacement, or refund of such devices or products, or require us to notify health professionals and others that the therapies, devices or products present unreasonable risks of substantial harm to the public health. Additionally, the FDA or similar foreign regulatory authorities may impose other operating restrictions, enjoin and restrain certain violations of applicable law pertaining to our devices and products and assess civil or criminal penalties against our officers, employees, or us. The FDA and similar foreign regulatory authorities have been increasing its scrutiny of the industry and the government is expected to continue to scrutinize the industry closely with inspections and possibly enforcement actions. Any adverse regulatory action, depending on its magnitude, may restrict us from effectively manufacturing, marketing and selling our devices and products, including the CellFX System. In addition, negative publicity and product liability claims resulting from any adverse regulatory action could have a material adverse effect on our financial condition and results of operations.

The continuing development of our CellFX System and other products depends upon maintaining strong working relationships with physicians.

The development, marketing, and sale of our CellFX System, and any future products in development, depends upon our ability to maintain strong working relationships with physicians. We rely on these professionals to provide us with considerable knowledge and experience regarding the development, marketing, and sale of our products. Physicians assist us in clinical trials and as researchers, marketing and product consultants and public speakers. If we cannot maintain our strong working relationships with these professionals and continue to receive their advice and input, the development and marketing of our products could suffer, which could harm our business, financial condition and results of operations. The medical device industry's relationship with physicians is under increasing scrutiny by the Office of Inspector General (OIG), the Department of Justice (DOJ), state attorneys general, and other foreign and domestic government agencies. Our failure to comply with laws, rules and regulations governing our relationships with physicians, or an investigation into our compliance by the OIG, DOJ, state attorneys general, and other government agencies, could significantly harm our business, including compromising the use or integrity of our clinical data in regulatory submissions to the FDA or similar regulatory authorities.

We are subject to healthcare and other laws and regulations relating to our business and could face substantial penalties if we are determined not to have fully complied with such laws, which could have an adverse impact on our business.

We are exposed to the risk that our employees and independent contractors, including principal investigators, consultants, any future commercial collaborators, service providers and other vendors may engage in misconduct or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or other unauthorized activities that violate applicable laws and regulations. There are many federal and state laws and regulations prohibiting fraud and abuse in the healthcare industry that can result in significant criminal and civil penalties. These laws may constrain the business or financial arrangements and relationships through which we conduct our operations, including how we research, market, sell, and distribute our products for which we obtain marketing approval or clearance. Such laws include:

- U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving, or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a federal healthcare program, such as Medicare and Medicaid. The term "remuneration" has been broadly interpreted to include anything of value, and the government can find a violation of the Anti-Kickback Statute without proving that a person or entity had actual knowledge of the law or a specific intent to violate it. In addition, the government may assert that a claim including items or services resulting from a violation of the U.S. federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act;

- U.S. federal civil and criminal false claims laws and civil monetary penalties laws, including the civil False Claims Act, which, among other things, impose criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the U.S. government, claims for payment or approval that are false or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or from knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the U.S. government;

- HIPAA imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for, healthcare benefits, items or services. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- HIPAA, as amended by HITECH, and its implementing regulations, also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information without appropriate authorization by covered entities subject to the rule, such as health plans, healthcare clearinghouses and healthcare providers as well as their business associates that perform certain services for or on their behalf involving the use or disclosure of individually identifiable health information;

- the U.S. Physician Payments Sunshine Act, which requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the government information related to payments or other "transfers of value" made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, and requires applicable manufacturers and group purchasing organizations to report annually to the government ownership and investment interests held by these physicians and their immediate family members;

- the CCPA, which went into effect in January 2020, requires covered companies to, among other things provide new disclosures to California consumers and afford such consumers new abilities to opt-out of certain sales of personal information. We cannot yet predict the impact of the CCPA or the recently approved CPRA on our business or operations, but it may require us to modify our data processing practices and policies and could cause us to incur substantial costs and expenses in an effort to comply;

- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers; and

- analogous state and non-U.S. laws and regulations, such as state anti-kickback and false claims laws, which may apply to our business practices, including, but not limited to, research, distribution, sales, and marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; state laws that require device companies to comply with the industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws and regulations that require manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures and pricing information; and state and non-U.S. laws governing the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

We have implemented compliance related programs and procedures to help identify and deter healthcare and other violations by employees and other third parties that perform services for us. Notwithstanding our efforts, however, it is possible that governmental authorities may conclude that our business practices do not comply with current or future statutes, regulations, agency guidance, or case law involving applicable healthcare or other applicable laws. In addition, we are subject to the risk that a person or government could allege violations of such laws, regulations and other obligations, or allege that fraud or other misconduct has taken place, even if no misconduct has occurred. If any such actions are instituted against us, those actions could have a significant impact on our business and financial results, including, without limitation, the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgements, possible exclusion from participation in Medicare, Medicaid and other U.S. healthcare programs, individual imprisonment, other sanctions, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations if we are not successful in defending ourselves or asserting our rights. Defending against any such actions can be costly, time-consuming and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. If any of the above occur, it could have a material adverse effect on our liquidity and financial condition.

Also, any material change to any of the laws or regulations applicable to our business could harm our business, financial condition and results of operations.

To obtain the necessary device approvals or clearances from regulatory authorities for our future product candidates, we will have to conduct various pre-clinical and clinical tests, which may be costly and time consuming, and may not provide results that will allow us to seek regulatory approval or clearance.

The number of pre-clinical and clinical tests that will be required for regulatory clearance or approval varies depending on the disease or condition to be treated, the method of treatment, the nature of the device, the jurisdiction in which we are seeking approval or clearance and the applicable regulations. Regulatory agencies, including those in the United States, Canada, Europe and other jurisdictions where medical devices and products are regulated, can delay, limit or deny approval of a product for many reasons. For example, regulatory agencies:

- may not deem a technology or device to be reasonably safe or effective for any intended use or indication;
- may interpret data from pre-clinical and clinical testing differently than we do;
- may determine our manufacturing facility or processes do not comply with quality system regulations;
- may conclude that our device does not meet quality standards for durability, long-term reliability, biocompatibility, electromagnetic compatibility, or electrical safety; or
- may change their approval or clearance policies or adopt new regulations in a manner that is adverse to us.

These regulators may make requests or disagree with us regarding the design or conduct of our clinical trials, resulting in an increased risk of difficulties or delays in obtaining regulatory approval or clearance on future product candidates and increased costs.

Even if a potential device or product ultimately is cleared or approved by the different regulatory authorities, it may be cleared or approved only for narrow indications which may render it commercially less viable.

Even if we complete clinical testing and a potential device or product of ours is cleared or approved, it may not be cleared or approved for the indications that are necessary or desirable for a successful commercialization. Regulators may grant marketing authorization contingent on the performance of costly additional clinical trials which may be required after approval or clearance. Regulators also may approve or clear our lead product candidates, including our CellFX System, for a more limited indication or a narrower patient population than we originally requested. Our preference will be to obtain as broad an indication as possible for use in connection with the particular disease or treatment for which it is designed. However, the final indication or labeling may be more limited than we originally seek. The limitation on use may make the device or product commercially less viable and more difficult, if not impractical, to market. Therefore, we may not obtain the revenues that we seek in respect of the proposed product, and we will not be able to become profitable and provide an investment return to our investors.

We will be subject to ongoing requirements and inspections that could lead to the restriction, suspension or revocation of our clearance.

We, as well as any potential third-party manufacturer, will be required to adhere to FDA quality systems, which include testing, control, and documentation requirements. We will be subject to similar regulations in foreign countries. Even when regulatory approval or clearance of a product is granted, the approval or clearance may be subject to limitations on the indicated uses for which the product may be marketed or to the conditions of approval or clearance, or contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the product. Ongoing compliance with quality system regulations and other applicable regulatory requirements is strictly enforced in the U.S. through periodic inspections by state and federal agencies, including the FDA, and in international jurisdictions by comparable agencies. Failure to comply with regulatory requirements could result in, among other things, warning letters, fines, injunctions, civil penalties, recall or seizure of products, total or partial suspension of production, failure to obtain premarket clearance or premarket approval for devices, withdrawal of approvals or clearances previously obtained, and criminal prosecution. The restriction, suspension or revocation of regulatory approvals or clearances, or any other failure to comply with regulatory requirements would limit our ability to operate and could materially increase our costs.

Because we and one of our licensors have used federal funding in the development of certain aspects of our technology, the federal government retains 'march-in' rights in connection with results derived from these grants.

March-in rights give the federal government the right to grant to other entities, which may include competitors, licenses or to take a license for itself if the government funded the development of a patent. The march-in right applies to patents that have been issued. The march-in right is intended to be used only if there is a threat to public health and safety that the owner of the patent is not equipped to handle. The march-in right may also be used to remove the exclusive rights belonging to a patent holder if the patent for which the government provided funding is not suitable for public use. If march-in rights are used by the government, the entities using the patent are required to pay royalties to the patent holder, which amount would be subject to negotiation. Because federal funding was used for some aspects of the company's technology that will be the subject of some of our patents, the company could be subject to the march-in right and lose its exclusivity of those patents, and may suffer direct competition if any license is granted by the government under the march-in right to a competitor.

Our employees, collaborators and other personnel may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements and insider trading.

We are exposed to the risk of fraud or other misconduct by or employees, collaborators and other personnel, which could include intentional, reckless and/or negligent conduct or disclosure of unauthorized activities to us that violates: (i) the laws of the FDA and other similar foreign regulatory bodies, including those laws requiring the reporting of true, complete and accurate information to such regulators; (ii) manufacturing standards; or (iii) healthcare fraud and abuse laws in the United States and similar foreign fraudulent misconduct laws. These laws may impact, among other things, future sales, marketing and education programs. The promotion, sales and marketing of healthcare items and services, as well as certain business arrangements in the healthcare industry, are subject to extensive laws designed to prevent fraud and abuse, kickbacks, self-dealing, and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, structuring and commissions, certain customer incentive programs, and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical trials.

We adopted a code of conduct applicable to all of our employees, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions. Whether or not we are successful in defending against any such actions or investigations, we could incur substantial costs, including legal fees, and divert the attention of management in defending ourselves against any of these claims or investigations, which could have a material adverse effect on our business and financial condition.

Healthcare policy changes, including recent federal legislation to reform the U.S. healthcare system, may have a material adverse effect on us.

Proposals by the federal government, state governments, regulators, and third-party payors to control or manage the increased costs of healthcare and to reform the U.S. healthcare system may impact our business significantly. Certain proposals could limit the prices we are able to charge for our products or the coverage and reimbursement available for our products and could limit the acceptance and availability of our products. The adoption of proposals to control costs could have a material adverse effect on our business and financial condition. We cannot predict the initiatives that may be adopted in the future or their full impact on our business. The continuing efforts of governments, insurance companies, managed care organizations, and other payors of healthcare services to contain or reduce costs of healthcare may negatively impact our ability to set a price that we believe is fair for our products, our ability to generate revenue and achieve profitability, and the availability of capital.

Risks Related to Owning Our Common Stock

The price of our common stock has been, and we expect it to continue to be, highly volatile, and you may be unable to sell your shares at or above the price you paid to acquire them.

The market price of our common stock has been highly volatile, and we expect it to continue to be highly volatile for the foreseeable future in response to many risk factors listed in this section, and others beyond our control, including:

- results of clinical trials of our planned products or those of our competitors;
- actions by regulatory bodies, such as the FDA, that affect our business or have the effect of delaying or rejecting approval or clearance of our planned products;
- actual or anticipated fluctuations in our financial condition and operating results;
- announcements by our customers, partners or suppliers relating directly or indirectly to our products, services or technologies;
- announcements of technological innovations by us or our competitors;
- changes in laws or regulations applicable to our CellFX System or to our planned products;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures, capital commitments, or achievement of significant milestones;
- additions or departures of key personnel;
- competition from existing products or new products that may emerge;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- disputes or other developments related to proprietary rights, including patents, litigation matters or our ability to obtain intellectual property protection for our technologies;
- actual or alleged security breaches;
-

announcements or expectations of additional financing efforts;

- sales of our common stock by us or our stockholders;
- stock price and volume fluctuations attributable to inconsistent trading volume levels of our shares;
- reports, guidance and ratings issued by securities or industry analysts;
- overall conditions in our industry and market including the negative impact of COVID-19 on the global economy and markets; and
- general economic and market conditions.

Any of the above may cause our stock price or trading volume to decline. Stock markets in general, and the market for companies in our industry in particular, have experienced price and volume fluctuations that have affected and continue to affect the market prices of equity securities of many companies. These fluctuations often have been unrelated or disproportionate to the operating performance of those companies. These broad market and industry fluctuations, as well as general economic, political and market conditions such as recessions, interest rate changes or international currency fluctuations, may negatively impact the market price of our common stock. Investors may not realize any return on their investment in us and may lose some or all of their investment. In the past, companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation. Securities litigation against us could result in substantial costs and divert our management's attention from other business concerns and adversely impact our ability to raise capital to fund our operations, which could seriously harm our business.

Sales or purchases of shares of our common stock may adversely affect the market for our common stock.

If we or our stockholders, particularly our directors, executive officers and significant stockholders, sell or purchase, register for sale, or indicate an intent to sell or purchase, shares of our common stock in the public market, it may have a material adverse effect on the market price of our common stock. In particular, Robert W. Duggan, our majority stockholder and Board Chairman, is not subject to any contractual restrictions with us on his ability to sell or transfer the shares of our common stock that he holds, and these sales or transfers could create substantial declines in the price of our securities or, if these sales or transfers were made to a single buyer or group of buyers, could contribute to a transfer of control of our company to a third party. Many of Mr. Duggan's Pulse shares have been registered for resale pursuant to an effective registration statement on Form S-3. Sales by Mr. Duggan of a substantial number of shares, or the expectation of such sales, could cause a significant reduction in the market price of our common stock.

Additionally, we may issue shares of common stock or securities convertible into, exchangeable or exercisable for our common stock from time to time in connection with financings, acquisitions, investments, or otherwise. Any such issuances would result in dilution to some or all of our existing stockholders and could cause our stock price to fall. We may also sell shares or other securities at a price per share that is less than the price per share paid by existing investors, and investors purchasing shares or other securities in the future could have rights superior to existing stockholders.

We do not know whether an active, liquid and orderly trading market will exist for our common stock and as a result it may be difficult for you to sell your common stock.

Prior to our initial public offering in May 2016, there was no public market for our common stock. Although our common stock is listed on The Nasdaq Capital Market (Nasdaq), the market for our shares has demonstrated varying levels of trading activity. As a result of these and other factors, you may not be able to sell your common stock quickly, at or above the price paid to acquire the stock or at all. Further, an inactive market may also harm our ability to raise capital by selling additional common stock and may harm our ability to enter into strategic collaborations or acquire companies or products by using our common stock as consideration.

Concentration of ownership by our principal stockholder limits your ability to influence the outcome of director elections and other transactions requiring stockholder approval.

A majority percentage of our outstanding stock is held by Robert W. Duggan, Chairman of our Board, who beneficially owns approximately 51% of our common stock outstanding as of the date of this Quarterly Report. As a result, Mr. Duggan has control over corporate actions requiring stockholder approval, including the following actions:

- to elect or defeat the election of our directors;
- to amend or prevent amendment of our certificate of incorporation or bylaws;
- to effect or prevent a merger, sale of assets or other corporate transaction; and
- to control the outcome of any other matter submitted to our stockholders for vote.

Additionally, because Mr. Duggan owns a majority of our outstanding shares, we are considered to be a "controlled" company under applicable Nasdaq rules. As such, we may voluntarily elect not to comply with certain of Nasdaq's corporate governance requirements, such as certain rules concerning the setting of executive compensation and the appointment of directors. Accordingly, during the period we remain a controlled company and during any transition period following a time when we are no longer a controlled company, you may not have the same protections afforded to stockholders of companies that are subject to all of the corporate governance requirements of the Nasdaq Stock Market. As a member of our Board, Mr. Duggan will adhere to the corporate governance standards adopted by the company.

Even though we have not yet elected to take advantage of any of these corporate governance exemptions permitted by Nasdaq, Mr. Duggan's stock ownership and our status as a "controlled" company may discourage a potential acquirer from making a tender offer or otherwise attempting to obtain control of our company, which in turn could reduce our stock price or prevent our stockholders from realizing a premium over our stock price. In addition, Mr. Duggan is not subject to any contractual restrictions on his ability to acquire additional shares of common stock and any such purchases, including purchases of equity securities in connection with any rights offerings or any alternative equity or equity-linked offering that we may conduct, could result in his acquisition of a larger percentage of our common stock.

Management currently beneficially holds a small percentage of our common stock. Other than their positions as directors or officers, and the restriction on the stockholders being able to call a special meeting limited to holders of 15% or more of the outstanding shares of common stock, our management will not be able to greatly influence corporate actions requiring stockholder approval.

Robert W. Duggan's controlling ownership position may impact our stock price and may deter or prevent efforts by other companies to acquire us, which could prevent our stockholders from realizing a control premium.

Robert W. Duggan is our Board Chairman, and beneficially owns approximately 51% of our common stock outstanding as of the date of this Quarterly Report. In addition, Mr. Duggan is not subject to any contractual restrictions on his ability to acquire additional shares of common stock, and any such purchases, including purchases of equity securities in connection with any rights offerings or any alternative equity or equity-linked offering that we may conduct, could result in his acquisition of a majority of our common stock. As a result of Robert W. Duggan's controlling ownership and position as Board Chairman, other companies may be less inclined to pursue an acquisition of us and therefore we may not have the opportunity to be acquired in a transaction that stockholders might otherwise deem favorable, including transactions in which our stockholders might realize a substantial premium for their shares. In addition, public speculation regarding Mr. Duggan, as well as our relationship with Mr. Duggan, could cause our stock price to fluctuate.

We have incurred and will continue to incur costs as a result of operating as a public company and our management has been and will be required to devote substantial time to public company compliance initiatives.

As a public company, listed in the United States, we have incurred and will continue to incur significant legal, accounting and other expenses due to our compliance with regulations and disclosure obligations applicable to us, including compliance with the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, as well as rules implemented by the SEC and Nasdaq. The SEC and other regulators have continued to adopt new rules and regulations and make additional changes to existing regulations that require our compliance.

Stockholder activism, the current political environment, and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact, in ways we cannot currently anticipate, the manner in which we operate our business. Our management and other personnel have and will continue to devote a substantial amount of time to these compliance programs and monitoring of public company reporting obligations and, as a result of the new corporate governance and executive compensation related rules, regulations, and guidelines prompted by the Dodd-Frank Wall Street Reform and Protection Act, or the Dodd-Frank Act, and further regulations and disclosure obligations expected in the future, we will likely need to devote additional time and costs to comply with such compliance programs and rules. New laws and regulations as well as changes to existing laws and regulations affecting public companies, including the provisions of the Sarbanes-Oxley Act, the Dodd-Frank Act, and rules adopted by the SEC and Nasdaq, will likely result in increased costs to us as we respond to their requirements. We are currently evaluating and monitoring developments with respect to these rules and regulations, and we cannot predict or estimate the amount of additional costs we may incur or the timing of such costs.

Furthermore, these and future rules and regulations could make it more difficult or more costly for us to obtain certain types of insurance, including director and officer liability insurance, and we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as our executive officers.

We are an "emerging growth company" under the JOBS Act as well as a "smaller reporting company"; as a result, we cannot be certain if the applicable reduced disclosure requirements will make our common stock less attractive to investors.

We are an "emerging growth company," as defined in the JOBS Act, and we may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not "emerging growth companies" including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. We also qualify as a "smaller reporting company," as defined in the Exchange Act, and so long as we remain a smaller reporting company, we benefit from and may take advantage of scaled disclosure requirements.

We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile and it may be difficult for us to raise additional capital as and when we need it. Investors may be unable to compare our business with other companies in our industry if they believe that our reporting is not as transparent as other companies in our industry. If we are unable to raise additional capital as and when we need it, our financial condition and results of operations may be materially and adversely affected. We will remain an "emerging growth company" until the end of 2021.

If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our market price and trading volume could decline.

The trading market for our common stock will depend on the research and reports that securities or industry analysts publish about us or our business. We do not have any control over these analysts. We currently have only limited analyst coverage of us and there can be no assurance that analysts will continue to cover us or provide favorable coverage. If one or more of the analysts who cover us downgrade our stock or change their opinion of our stock, our market price would likely decline. If analysts cease coverage of our company or fail to regularly publish reports on us, we could lose visibility in the financial markets, which could cause our share price or trading volume to decline.

We have not paid dividends in the past and have no plans to pay dividends.

For the foreseeable future, we plan to reinvest all of our earnings, to the extent we have earnings, into our product research and development efforts, so we have no plans to pay any cash dividends with respect to our securities. We cannot assure you that we would, at any time, generate sufficient surplus cash that would be available for distribution to the holders of our common stock as a dividend. Therefore, you should not expect to receive cash dividends on our outstanding common stock.

Anti-takeover provisions in our charter documents and under Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management and limit the market price of our common stock.

Certain anti-takeover provisions of Delaware law and provisions in our certificate of incorporation and bylaws may have the effect of delaying or preventing a change of control or changes in our management. These provisions could also make it difficult for stockholders to elect directors that are not nominated by the current members of our board of directors or take other corporate actions, including effecting changes in our management. Our certificate of incorporation and bylaws include provisions that:

- authorize our board of directors to issue, without further action by the stockholders, up to 50,000,000 shares of preferred stock and up to approximately 500,000,000 shares of authorized but unissued shares of common stock;
- require that any action to be taken by our stockholders be effected at a duly called annual or special meeting and not by written consent;
- specify that special meetings of our stockholders can be called only by our board of directors, the chairman of our board of directors, any of our officers, or any stockholder holding at least fifteen percent (15%) of the voting power of the capital stock issued and outstanding and entitled to vote;
- establish an advance notice procedure for stockholder approvals to be brought before an annual meeting of our stockholders, including proposed nominations of persons for election to our board of directors;
- require the affirmative vote of holders of at least 66 2/3% of the voting power of all the then outstanding shares of our voting stock, voting together as a single class, to amend provisions of our certificate of incorporation or our bylaws;
- give our board of directors the ability to amend our bylaws by majority vote; and
- provide that vacancies on our board of directors may be filled only by a majority of directors then in office, even though less than a quorum.

These provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our Board, which is responsible for appointing the members of our management. Furthermore, our bylaws provide that unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware shall, to the fullest extent permitted by law, be the sole and exclusive forum for (a) any derivative action or proceeding brought on behalf of us, (b) any action asserting a claim of breach of fiduciary duty owed by any director, officer or other employee of us to us or our stockholders, (c) any action asserting a claim arising pursuant to any provision of the Delaware General Corporation Law, our certificate of incorporation or our bylaws, or (d) any action asserting a claim governed by the internal affairs doctrine, in each case subject to the Court of Chancery having personal jurisdiction over the indispensable parties named as defendants therein; provided that, if and only if the Court of Chancery dismisses any such action for lack of subject matter jurisdiction, such action may be brought in another state or federal court sitting in Delaware. Our bylaws further provide that the federal district courts of the United States of America will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. Any person or entity purchasing or otherwise acquiring any interest in any of our securities shall be deemed to have notice of and consented to these provisions. These exclusive-forum provisions may discourage lawsuits against us or our directors, officers, and employees. In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which limits the ability of stockholders owning in excess of 15% of our outstanding voting stock to engage in certain types of transactions with us.

General Risk Factors

Unfavorable global economic or political conditions could adversely affect our business, financial condition or results of operations.

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets, including the negative impact of COVID-19 on the global economy and markets. Furthermore, the market for aesthetic medical treatments may be particularly vulnerable to unfavorable economic conditions. A global financial crisis or a global or regional political disruption could cause extreme volatility in the capital and credit markets, as has recently been the case due to COVID-19. A severe or prolonged economic downturn or political disruption could result in a variety of risks to our business, including weakened demand for our lead product, the CellFX System, or any future product candidates, if approved, and our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy or political disruption could also strain our manufacturers or suppliers, possibly resulting in supply disruption, or cause our customers to delay making payments for our services. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the political or economic climate and financial market conditions could adversely impact our business.

If we experience material weaknesses in the future or otherwise fail to maintain an effective system of internal control over financial reporting in the future, we may not be able to accurately or timely report our financial condition or results of operations, which may adversely affect investor confidence in us and, as a result, the value of our common stock.

As a public company, we are required to maintain internal control over financial reporting and to report any material weaknesses in such internal controls. Section 404 of the Sarbanes-Oxley Act requires that we evaluate and determine the effectiveness of our internal control over financial reporting and provide a management report on internal control over financial reporting. A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our financial statements will not be prevented or detected on a timely basis. Ensuring that we have adequate internal financial and accounting controls and procedures in place so that we can produce accurate financial statements on a timely basis is a costly and time-consuming effort. Our internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with U.S. GAAP. We may not be able to complete our evaluation, testing and any required remediation in a timely fashion. During the evaluation and testing process, if we identify one or more material weaknesses in our internal control over financial reporting, we will be unable to assert that our internal controls are effective. The identification of one or more material weaknesses would preclude a conclusion that we maintain effective internal control over financial reporting. Accordingly, there could continue to be a reasonable possibility that a material misstatement of our financial statements would not be prevented or detected on a timely basis.

We are required to disclose changes made in our internal control and procedures on a quarterly basis. However, our independent registered public accounting firm will not be required to report on the effectiveness of our internal control over financial reporting pursuant to Section 404 of the Sarbanes-Oxley Act until we are no longer an “emerging growth company” as defined in the Jumpstart Our Business Startups Act (JOBS Act), which will occur at the end of 2021, or a “small reporting company”. At such time, our independent registered public accounting firm may issue a report that is adverse in the event it is not satisfied with the level at which our controls are documented, designed or operating. Our remediation efforts may not enable us to avoid a material weakness in the future. If we are unable to assert that our internal control over financial reporting is effective, or when required in the future, if our independent registered public accounting firm is unable to express an unqualified opinion as to the effectiveness of our internal control over financial reporting, investors may lose confidence in the accuracy and completeness of our financial reports and the market price of our common stock could be adversely affected, and we could become subject to investigations by the stock exchange on which our securities are listed, the SEC, or other regulatory authorities, which could require additional financial and management resources.

We may become involved in litigation that may materially adversely affect us.

From time to time, we may be involved in a variety of claims, lawsuits, investigations, or proceedings relating to securities laws, product liability, patent infringement, contract disputes, and other matters relating to various claims that arise in the normal course of our business in addition to governmental and other regulatory investigations and proceedings. In addition, third parties may, from time to time, assert claims against us. Such matters can be time-consuming, divert management's attention and resources, cause us to incur significant expenses or liability and/or require us to change our business practices. Because of the potential risks, expenses and uncertainties of litigation, we may, from time to time, settle disputes, even where we have meritorious claims or defenses, by agreeing to settlement agreements. Because litigation is inherently unpredictable, we cannot assure you that the results of any of these actions will not have a material adverse effect on our business, financial condition, results of operations and prospects. See the section entitled "Legal Proceedings" for more detail on our current legal proceedings.

Our business may be adversely affected by health epidemics including the coronavirus pandemic.

The COVID-19 pandemic has resulted in government authorities implementing numerous measures to try to contain the virus, such as travel bans and restrictions, quarantines, shelter-in-place or stay-at-home orders, and business shutdowns.

For most of 2020 and the first half of 2021, we required, in accordance with local and state guidelines regarding the COVID-19 pandemic, all of our employees to work remotely unless they could not perform their essential functions remotely. We also suspended all non-essential travel for our employees. While many of our employees are accustomed to working remotely or working with other remote employees, much of our workforce has not historically been remote. We continue to monitor the situation and may adjust our current policies as more information and public health guidance becomes available. Operational restrictions as a result of the COVD-19 pandemic, could harm our business, financial condition and results of operations.

In addition, our clinical trials may be affected by the continuing COVID-19 pandemic. Site initiation and patient enrollment may be delayed, for example, due to prioritization of hospital resources toward the COVID-19 pandemic, travel restrictions imposed by governments, and the inability to access sites for initiation and monitoring. Also, some of our suppliers of certain materials used in the production of our CellFX System are located in areas impacted by COVID-19 which could limit our ability to obtain sufficient materials. COVID-19 has and will continue to adversely affect global economies and financial markets of many countries, resulting in an economic downturn that could affect demand for our CellFX System and other product candidates, if approved, and impact our operating results. Even after the COVID-19 pandemic has subsided, we may continue to experience an adverse impact to our business as a result of the continued global economic impact of the pandemic. Although we are continuing to monitor and assess the effects of the COVID-19 pandemic on our business, the ultimate impact of the COVID-19 pandemic or a similar health epidemic is highly uncertain and subject to change.

Our facilities in California are located near known earthquake faults, and the occurrence of an earthquake or other catastrophic disaster could cause damage to our facilities and equipment, which could require us to cease or curtail operations.

Our facilities in Hayward, California are located near known earthquake fault zones and are vulnerable to damage from earthquakes. We are also vulnerable to damage from other types of disasters, including fire, floods, power loss, communications failures, and similar events. If any disaster were to occur, our ability to operate our business at our facilities would be seriously, or potentially completely, impaired. In addition, the nature of our activities could make it difficult for us to recover from a natural disaster. The insurance we maintain may not be adequate to cover our losses resulting from disasters or other business interruptions. Accordingly, an earthquake or other disaster could materially and adversely harm our ability to conduct business.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

During the last fiscal quarter, we completed no unregistered sale of our securities, except for the sale of approximately three million shares of our common stock, in a private placement, as described elsewhere in this Quarterly Report and in our Form 8-K filed on July 1, 2021.

Item 3. Default Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

None.

Item 6. Exhibits

Exhibit Number	Exhibit Description
10.1	Securities Purchase Agreement, dated June 30, 2021, by and between Pulse Biosciences, Inc. and Robert W. Duggan (incorporated herein by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, Commission File No. 001-37744, filed on July 1, 2021).
31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certification of the Chief Executive and Chief Financial Officers pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. Section 1350).
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)

* The certification attached as Exhibit 32.1 that accompanies this Quarterly Report is deemed furnished and not filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Pulse Biosciences, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Quarterly Report, irrespective of any general incorporation language contained in such filing.

Signatures

Pursuant to the requirements of the Securities Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

PULSE BIOSCIENCES, INC.

Date: August 9, 2021

By: /s/ Sandra A. Gardiner
Sandra A. Gardiner
Chief Financial Officer, Executive Vice President of Finance and Administration, Secretary and Treasurer
(*Principal Financial and Accounting Officer*)

Exhibit 31.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER PURSUANT TO SECURITIES EXCHANGE ACT RULES 13a-14(a) and 15d-14(a), AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Darrin R. Uecker, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the quarter ended June 30, 2021 of Pulse Biosciences, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 9, 2021

By: /s/ Darrin R. Uecker
Darrin R. Uecker
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER PURSUANT TO SECURITIES EXCHANGE ACT RULES 13a-14(a) and 15d-14(a), AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Sandra A. Gardiner, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the quarter ended June 30, 2021 of Pulse Biosciences, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 9, 2021

By: /s/ Sandra A. Gardiner
Sandra A. Gardiner
Chief Financial Officer, Executive Vice President of Finance and Administration, Secretary and Treasurer
(Principal Financial and Accounting Officer)

Exhibit 32.1

CERTIFICATIONS PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Pulse Biosciences, Inc. (the "Company") on Form 10-Q for the period ended June 30, 2021 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of the undersigned certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of his knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

In Witness Whereof, the undersigned have set their hands hereto as of the 9th day of August 2021.

/s/ Darrin R. Uecker
Darrin R. Uecker
President and Chief Executive Officer
(Principal Executive Officer)

/s/ Sandra A. Gardiner
Sandra A. Gardiner
Chief Financial Officer, Executive Vice President of Finance and Administration, Secretary and Treasurer
(Principal Financial and Accounting Officer)

This certification is deemed furnished and not filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Pulse Biosciences, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this report, irrespective of any general incorporation language contained in such filing.